



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

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**REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)**

*(Prepared by the electronic working group led by New Zealand, France and Indonesia)*

## **INTRODUCTION**

At the 38<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU38), the Committee agreed to establish an electronic working group (eWG) chaired by New Zealand, co-chaired by Indonesia and France and working in English only with the following terms of reference:

### **Terms of Reference for the electronic working group:**

- Finalise the minimum protein requirements and levels for the optional addition of DHA on the Essential Composition of Follow-up Formula for older infants (6-12 months) (Sub-section 3 of Section A);
- Finalise the outstanding requirements for the Essential Composition of product for young children (12-36 months) (Sub-section 3 of Section B);
- Finalise the product definitions contained within Definition 2.1 including the name of product for 12-36 months;
- Review the Scope and Labelling Sections with a point of differentiation at 12 months, for Section A and Section B of the draft Standard based on the discussions at CCNFSDU38, and propose draft text.

Further to this, all other requirements on which agreement has been reached are at Step 4.

The proposed timeline for the development of the draft standard would be: adoption at Step 5 in 2018 with a view to adoption by CAC in July 2019. The CCEXEC would be informed accordingly.

**Table of Contents**

<b>1</b>	<b>Conduct of the Electronic Working Group (eWG) 2017</b>	<b>3</b>
	<b>CONCLUSIONS</b>	<b>3</b>
1.1	Structure and name of the Standard	3
1.2	Work for further consideration	3
1.3	Timeline	5
	<b>DISCUSSION AND RECOMMENDATIONS OF EWG (APPENDIX I)</b>	<b>6</b>
1.4	Overview	6
1.5	Protein	6
1.6	Optional addition: Docosahexaenoic acid	10
<b>2</b>	<b>ESSENTIAL COMPOSITION OF [NAME OF PRODUCT] FOR YOUNG CHILDREN (12-36 MONTHS)</b>	<b>13</b>
2.1	Overview	13
2.2	Energy contribution from macronutrients	14
2.3	Protein Quality	14
2.4	Minimum total fat	15
2.5	Carbohydrate	16
2.6	Sugars, other than lactose, and other sweet tasting carbohydrates	17
2.7	Calcium-to-phosphorous ratio	23
2.8	Vitamin D	24
<b>3</b>	<b>PREAMBLE</b>	<b>25</b>
3.1	Overview	25
3.2	Background	25
3.3	Proposed approach	26
<b>4</b>	<b>SCOPE AND LABELLING</b>	<b>26</b>
4.1	Overview	26
4.2	Scope - Background	27
4.3	Labelling – Background	27
<b>5</b>	<b>SCOPE AND LABELLING – OLDER INFANTS (6-12 MONTHS)</b>	<b>28</b>
5.1	Classification of Product	28
5.2	Scope – Individual Provisions	29
5.3	Labelling – Introductory Paragraph	32
5.4	Labelling - Name of the Product	35
5.5	Labelling - List of Ingredients	37
5.6	Labelling – Declaration of Nutritive Value	38
5.7	Labelling – Date Marking and Storage Instructions	40
5.8	Labelling – Information for Use	40
5.9	Labelling – Additional Labelling Requirements	45
<b>6</b>	<b>SCOPE AND LABELLING – YOUNG CHILDREN (12-36 MONTHS)</b>	<b>48</b>
6.1	Classification of Product	49
6.2	Scope – Individual provisions	49
6.3	Labelling – Introductory Paragraph	53
6.4	Labelling – Name of the Product	56
6.5	Labelling – List of Ingredients	58
6.6	Labelling – Declaration of Nutritive Value	59
6.7	Labelling – Date Marking and Storage Instructions	60
6.8	Labelling – Information for Use	61
6.9	Labelling – Additional Labelling Requirements	65
<b>7</b>	<b>DEFINITIONS</b>	<b>69</b>
7.1	Product definition – follow-up formula for older infants	69
7.2	Product definition – [Name of product] for young children	70
<b>8</b>	<b>NAME OF PRODUCTS</b>	<b>73</b>
8.1	Name of product for older infants	73
8.2	Name of product for young children	73
<b>9</b>	<b>REFERENCES</b>	<b>75</b>
	<b>Appendix II</b>	<b>77</b>
	<b>Appendix III</b>	<b>92</b>

## 1 Conduct of the Electronic Working Group (eWG) 2017

The eWG (list of participants is presented in Appendix III) has considered five consultation papers during 2017. Two consultation papers were prepared to address the remaining compositional aspects of the two product categories, one for follow-up formula for older infants and the other one for [name of product] for young children. These consultation papers were posted on the Codex online platform in March 2017 for an eight week consultation period. For follow-up formula for older infants the discussions centred on the minimum level of protein and the level of optional addition of docosahexaenoic acid. For [name of product] for young children, the main aspects were establishing minimum level for fat, maximum level for available carbohydrates as well as additional restrictions for the addition of sugars to the product. Additional topics addressed were the need of a calcium-phosphorous ratio and addition of vitamin D.

With respect to the Scope, Labelling and Definition aspects of the Standard, three papers were posted on the Codex online platform during 2017 for eWG comment. The focus of the 1<sup>st</sup> Consultation Paper was to consider these aspects of the Standard noting the need to differentiate between follow-up formula for older infants and [name of product] for young children. The 1<sup>st</sup> Consultation Paper also discussed the name and definitions for the respective products.

For the second round of consultation, two separate papers were prepared on the Scope, Labelling and Definition aspects for the respective products. The purpose of this approach was to assist in differentiation of the two products by considering the Scope and Labelling aspects separately for each product category. This approach complemented that taken for the compositional requirements of the two products where there is a point of differentiation at 12 months.

Please note the following abbreviations used throughout this paper:

CM: Codex Member                      CMO: Codex Member Organisation              CO: Codex Observer

eWG: Electronic Working Group

Infant Formula Standard: Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-181)

### CONCLUSIONS

The Chairs of the eWG have used feedback from the eWG consultations to prepare this Agenda Paper, which contains 37 recommendations covering the composition, preamble, scope, labelling and definitions for both follow-up formula for older infants and [name of product] for young children (Appendix I).

The Chairs are of the view that the Committee has been provided with a significant amount of data and sufficient opportunity to finalise their decisions on the essential composition of follow-up formula for older infants, and for [name of product] for young children. The Committee is also in a position to agree to many of the scope and labelling provisions, as a result of the progress made by the 2017 eWG, and to finalise the names of the products and the product definitions. A draft Standard has been provided at Appendix II to support discussions.

Some outstanding issues to be considered in future review of the Standard

#### 1.1 Structure and name of the Standard

Still outstanding is a decision on the final structure of the Standard. This in turn will inform the name of the Standard based on what products are covered.

#### 1.2 Work for further consideration

Additional sections that are included within the Infant Formula Standard and/or the current Follow-up Formula Standard and which are yet to be discussed and progressed are as presented below. Many of the Sections refer to other Codex Standards or Guidelines that are applicable.

#### Purity Requirements

The current Follow-up Formula Standard states that; *'All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour'*. This requirement is the same as that contained within the Infant Formula Standard with the exception of the age range.

- **Vitamin Compounds and Mineral Salts**

Both the Infant Formula Standard and the current Follow-up Formula Standard reference the *Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* ([CAC/GL 10-1979](#)). The Infant Formula and Follow-up Formula Standards state that vitamins and minerals added in accordance with the essential and optional compositional provisions of the respective standards should be selected from this Advisory List.

- **Consistency and Particle Size**

The current Follow-up Formula Standard states that; *'When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles'*. The Infant Formula Standard includes this requirement and further states that it must be *'suitable for adequate feeding of young infants'*.

- **Specific Prohibitions**

Both the Infant Formula and Follow-up Formula Standard only have one prohibition listed. That is, *'the product and its components shall not have been treated by ionizing radiation'*.

- **Food Additives**

The current Follow-Up Formula Standard lists which additives are permitted and states that the carry-over principle (Section 1.4) of the General Standard for Food Additives ([CODEX STAN 192-1995](#)) shall apply. The Infant Formula Standard includes a more comprehensive list with INS numbers.

- **Contaminants**

The Infant Formula Standard states that; *'The products covered by this Standard shall comply with the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed* ([CODEX STAN 193-1995](#)), and that *'the products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius'*. Commission. The current Follow-up Formula Standard does not reference CODEX STAN 193-1995, and instead includes a requirement for preparation of product under good manufacturing practices.

- **Hygiene**

The current Follow-up Formula Standard references the relevant provisions of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* ([CAC/RCP 66-2008](#)). In addition, the Infant Formula Standard references the *General Principles of Food Hygiene* ([CAC/RCP 1-1969](#)), and the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* ([CAC/GL 21-1997](#)).

- **Packaging**

Both the Infant Formula Standard and the current Follow-up Formula Standard include the same two requirements for packaging which state that: *'The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media'*, and that *'the containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply'*.

- **Fill of Container**

Both the Infant Formula Standard and the current Follow-up Formula Standard contain the same requirement for fill of containers.

- **Methods of Analysis and Sampling**

The current Follow-up Formula Standard advises referring to relevant Codex texts on methods of analysis and sampling, whereas the Infant Formula Standard specifically references the *Recommended Methods of Analysis and Sampling* ([CODEX STAN 234-1999](#)), and states that relevant provisions shall be used. CCMAS agreed to have CODEX STAN 234-1999 as the single reference for methods of analysis in Codex standards and CAC39 adopted amendments to the Procedural Manual *"Format for Codex Commodity Standards"* to this effect.

### 1.3 Timeline

Below is the proposed timeline for completion of this work. Please note that this timeline is dependent on the outcomes of Committee discussions and progress made at CCNFSDU39 and may need to be modified.

December 2017	Consideration of the draft standard and advancement of the composition, scope and labelling sections to Step 5
December 2018	Completion of the standard and advancement to Step 8 for adoption by CAC.
July 2019	CAC adoption of draft standard

Recommendation:

The committee is invited to:

- consider the recommendations of the eWG (see Appendix I); and
- the proposed timeline for completion of work (as presented above).

## APPENDIX I

## DISCUSSION AND RECOMMENDATIONS OF EWG

(Comments at Step3 on Recommendations 1-37 are requested through [CL 2017/75-NFSDU](#).)

## ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS (6-12 MONTHS)

The focus of the Consultation Paper on Essential Composition: Follow-up Formula for Older Infants circulated in March was to consider the outstanding compositional aspects of the Standard for Follow-up Formula for the age group 6-12 months.

Thirty two responses were received to the Consultation Paper:

26 Codex Member Countries (CM)

1 Codex Member Organisation (CMO) – representing 28 Member States

5 Codex Observers (CO)

## 1.4 Overview

At CCNFSDU38 almost all of the requirements for the essential composition of follow-up formula for older infants were progressed to Step 4.

The outstanding areas which remain at Step 3 relate to the minimum protein requirement and associated footnotes 5 and 6, and the conversion of the requirements for the optional addition of docosahexaenoic acid (DHA) from percentage total fatty acids to mg/100 kcal (REP17/NFSDU, Appendix IV, text in square brackets). The term of reference related to this section of the draft standard is as follows:

- Finalise the minimum protein requirements and levels for the optional addition of DHA on the Essential Composition of follow-up formula for older infants (6-12 months) (Sub-Section 3 of Section A).

## 1.5 Protein

At CCNFSDU38 the Committee agreed to a maximum protein value of 3.0 g/100 kcal and the wording of footnotes 2 - 4. The Committee agreed to postpone the decision on a minimum level for protein and associated footnotes until the next session, mindful that a European Food Safety Authority (EFSA) Scientific Opinion on this issue was in progress at the time. A draft of the EFSA Scientific Opinion on the safety and suitability for use by infants of follow-up formula with a protein content of at least 1.6 g/100 kcal was published in March 2017 shortly before the circulation of the Consultation Paper on the Essential Composition of Follow-up Formula for Older Infants and was summarised and presented in this Consultation Paper.

The current draft standard states the following with regards to protein requirements:

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.8] <sup>5),6)</sup>	3.0	-
g/100 kJ	[0.43] <sup>5),6)</sup>	0.72	-

<sup>2)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>3)</sup> For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

<sup>4)</sup> Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

<sup>5)</sup> The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of [2.25 g/100 kcal (0.5 g/100 kJ)] applies.

<sup>6)</sup> Follow-up formula based on non-hydrolysed milk protein containing [1.61 – 1.8 g] protein/100 kcal should be clinically evaluated by a competent national and/or regional authority. Follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].

### 1.5.1 Minimum protein level in follow-up formula for older infants

#### EFSA Scientific Opinion

EFSA published its [scientific opinion](#) on the safety and suitability for use by infants of follow-up formula with a protein content of at least 1.6 g/100 kcal but meeting all other relevant EU legislation requirements in May 2017 (EFSA 2017). The conclusions of the draft opinion that were summarised in the Consultation Paper and available to the eWG to consider during the eight week consultation period from mid-March to mid-May did not change in the subsequent final scientific opinion.

The EFSA Panel assessed the safety and suitability of lower protein follow-up formula based on various sources of protein, including: cows' milk intact protein, goats' milk intact protein, soy protein isolates and protein hydrolysates. In order to assess the safety and suitability of follow-up formula for older infants, the following aspects were considered:

- a) The dietary protein requirements of infants in the second half of the first year of life;
- b) The protein content of breast-milk during the first year of lactation;
- c) Dietary protein intake of infants in Europe from breast-milk, formula and complementary food;
- d) The overall contribution that a follow-up formula with a protein content of 1.6 g/100 kcal could make towards protein requirements in the target population, assuming access to complementary food of a sufficient quality, following established guidelines in Europe;
- e) The application submitted by the food business operator, including two intervention studies in healthy term infants.

The overall conclusion of EFSA's assessment was that the use of follow-up formula for older infants with a protein content of at least 1.6 g/100 kcal from milk protein (cows' or goats') that otherwise comply with EU legislation is safe and suitable for infants living in Europe with access to complementary foods of a sufficient quality.

EFSA's final scientific opinion is accompanied by a document summarising the outcome of the public consultation carried out on the draft scientific opinion (EFSA 2017b). This document, [Outcome of a public consultation on a draft scientific opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal](#), states that:

*“The Panel considers, however, that the conclusions of the opinion (i.e. that the use of FOF with a protein content of at least 1.6 g/100 kcal from intact cow's milk protein or intact goat's milk protein otherwise complying with the requirements of relevant EU legislation is safe and suitable for infants living in Europe with an intake of complementary foods of a sufficient quality) could be generalised to healthy infants with comparable dietary intakes from all sources (breastmilk, formula and CF) living in other countries.”*

The available data did not allow EFSA to establish the safety and suitability of follow-up formula with a similar protein content made from soy protein isolates or protein hydrolysates.

#### **Non-European surveys measuring protein intake of older infants**

Given that the EFSA opinion cannot be generalised to countries where protein intakes may be lower and/or of poorer quality, unconditional acceptance of a protein content of 1.6g/ 100 kcal for follow-up formula for older infants does not seem warranted globally.

The eWG members were asked if they were aware of any other non-European dietary surveys which had not been considered previously by the eWG and which have reported protein intakes of older infants. The eWG members reported in total an additional six national surveys from five countries, and five studies. These are listed below.

#### **National surveys**

Ecuador: National Health and Nutrition Survey 2012 (Encuesta Nacional de Salud y Nutricion-Ecuador [ENSANUT-ECU]) [http://www.ecuadorencifras.gob.ec/documentos/web-inec/Estadisticas\\_Sociales/ENSANUT/MSP\\_ENSANUT-ECU\\_06-10-2014.pdf](http://www.ecuadorencifras.gob.ec/documentos/web-inec/Estadisticas_Sociales/ENSANUT/MSP_ENSANUT-ECU_06-10-2014.pdf) (in Spanish).

India: National Nutrition Monitoring Bureau Report of Third Repeat Survey, National Institute of Nutrition, Indian Council of Medical Research, 2012 (hard copy only).

Japan: Dietary Reference Intakes for Japanese (2015) <http://www.mhlw.go.jp/stf/shingi/0000041824.html> (in Japanese) Overview in English: <http://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/Overview.pdf>

Peru: The National Centre for Food and Nutrition of the National Health Institute - Ministry of Health (CENAN-INS) Technical Report: "Food consumption in Peruvian children ages 6 to 35 months; 2012-2013". <http://www.ins.gob.pe/repositorioaps/0/5/er/estudiosconsumo/VIN20122013.pdf> (in Spanish).

Peru: The National Centre for Food and Nutrition of the National Health Institute - Ministry of Health (CENAN-INS) Technical report: "Consumption of Foods in Peruvian Children from 6 to 35 months; 2013-2014". <http://www.portal.ins.gob.pe/es/component/rsfiles/preview?path=cenan%252FVigilancia%2Bde%2BIndicadores%2BNutricionales%2BB%252FVIN20132014171215.pdf> (in Spanish).

Philippines: Reference Food and Nutrition Research Institute-Department of Science and Technology. 2015. Philippine Nutrition Facts and Figures 2013. 8th National Nutrition Survey (hard copy only).

## **Studies**

Arsenault JE, Brown KH. (2017) Dietary protein intake in young children in selected low-income countries is generally adequate in relation to estimated requirements for healthy children, except when complementary food intake is low. *Journal of Nutrition* Feb 2017 <http://jn.nutrition.org/content/early/2017/02/15/jn.116.239657>

Castro TG, Baraldi LG, Muniz PT, Cardoso MA. Dietary practices and nutritional status of 0-24-month-old children from Brazilian Amazonia. *Public Health Nutr.* 2009 Dec;12(12):2335-42. <https://www.ncbi.nlm.nih.gov/pubmed/19257920>

Conn JA, Davies MJ, Walker RB, Moore VM. Food and nutrient intakes of 9-month-old infants in Adelaide, Australia. *Public Health Nutr.* 2009 Dec;12(12):2448-56. <https://www.ncbi.nlm.nih.gov/pubmed/19402944>

Lee, DE. (2014) Children's protein consumption in Southeast Asia: consideration of quality as well as quantity of children's protein consumption in Southeast Asia. Wharton Research Scholars. The Wharton School, University of Pennsylvania. 115. [http://repository.upenn.edu/wharton\\_research\\_scholars/115](http://repository.upenn.edu/wharton_research_scholars/115).

Lioret S, McNaughton SA, Spence AC, Crawford D, Campbell KJ. Tracking of dietary intakes in early childhood: the Melbourne Infant Program. *Eur J Clin Nutr.* 2013 Mar;67(3):275-81. <https://www.ncbi.nlm.nih.gov/pubmed/23321573>

The Chairs have not analysed the surveys due to not having access to them or them not being available in English. The studies provided by the eWG members do not report protein intake at lower percentiles (P2.5<sup>th</sup>, P5<sup>th</sup>, P10<sup>th</sup>).

## **eWG views on minimum protein level**

There was almost unanimous support (24 CM, 1 CMO, 2 CO) for the approach put forward by the Chairs in the Consultation Paper that footnote 6 would specify that evaluation by a competent national/regional authority is required to ensure safety and suitability of follow-up formula based on non-hydrolysed milk protein containing 1.6-1.8 g protein / 100 kcal. The Chairs note the unintentional deletion of the word clinically in the question box in both the Consultation Paper and the submission form. However, three of the eWG members (2 CM, 1 CO) were of the view that clinical evaluation is the responsibility of the formula manufacturer rather than of national/regional authorities.

Other suggestions made by eWG members for the footnotes included:

*Follow-up formula based on non-hydrolysed milk protein containing less than 1.8 g protein / 100 kcal should be clinically evaluated **unless a competent national and/or regional authority considers otherwise taking into account its own assessment of the evidence and the nutritional needs of the local population.***

*Follow-up formula based on non-hydrolysed milk protein containing 1.6 -1.8 g protein /100 kcal or based on hydrolysed protein containing less than 2.25 g protein / 100 kcal should be evaluated by a competent national and/or regional authority to ensure its safety and suitability. **The suitability shall be demonstrated by the food business operator through a systematic review of the available data relating to the expected benefits and to safety consideration as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. Evaluation on hydrolysed protein should be based on clinical studies.***

*Follow-up formula based on non-hydrolysed milk protein containing 1.6-1.8 g protein /100 kcal **should be scientifically substantiated and when needed clinically evaluated.***

A number of eWG members (2 CM, 1 CMO, 2 CO) suggested that the minimum value could be placed in the table itself instead of being mentioned in the footnote. When a minimum or a maximum value is set for a given substance, it is commonly laid down in the main text of the provision. Footnotes provide further details on how this provision is to be applied, if required. This is done in the Infant Formula Standard where the minimum protein level of 1.8 g/100kcal is presented in the table and further conditions to it are mentioned in the footnote:



“<sup>6</sup>Infant formula based on non-hydrolysed milk protein containing less than 2 g protein/ 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated.”

### 1.5.2 Footnote 5: Minimum protein level in formula based on soy protein isolate

#### eWG views

There was unanimous support from eWG members (25 CM, 1 CMO, 2 CO) to retain the minimum protein requirement of 2.25 g/100 kcal (0.5 g/100 kJ) for follow-up formula for older infants based on soy protein isolate. There is no new evidence to modify the level. Several members commented that the second sentence should be amended to align with the first by the addition of ‘non-goats’ milk protein’.

### 1.5.3 Footnote 6: Minimum protein level in formula based on hydrolysed protein

#### eWG views

There was strong support from the eWG (22 CM, 1 CMO, 2 CO) to retain the wording of the footnote to specify that follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal should be clinically evaluated.

The suggestion was also made by some members to combine the two sentences relating to the clinical evaluation of formula based on non-hydrolysed milk protein containing 1.6-1.8 g/protein and formula based on hydrolysed protein containing less than 2.25 g/protein/100 kcal in footnote 6.

A further suggestion was made that the word *partially* should be inserted to distinguish these products from products that contain extensively hydrolysed proteins that are used in formulas for special medical purposes for use in infants who are allergic to cow’s milk proteins.

Some eWG members were of the opinion that all hydrolysed protein based formulas should be clinically evaluated, not just those with less than 2.25 g protein/100 kcal. The justification given for this was that the scientific evidence does not support using follow-up formula based on hydrolysed protein as an option for prevention of allergic diseases during the second half year of infancy when complementary feeding usually provides intact proteins from cow’s milk and other sources. Hence, there would not be a justification for using hydrolysed protein in follow-up formula intended for healthy older infants. It was also mentioned that the safety and suitability of infant formula containing protein hydrolysates have not been fully demonstrated.

#### Conclusions on protein requirements

The EFSA Scientific Opinion (EFSA 2017) concluded that the use of follow-up formula with a protein content of at least 1.6 g/100 kcal from intact cow’s milk protein or intact goat’s milk protein is safe and suitable for infants living in Europe with an intake of complementary foods of a sufficient quality and could be generalised to healthy infants with comparable dietary intakes living in other countries. However, given that the EFSA opinion cannot be generalised to countries where protein intakes may be lower and/or of poorer quality, unconditional acceptance of lower protein does not seem warranted.

The current drafting of the standard specifies a minimum protein content of 1.8 g/100 kcal with an associated footnote clarifying that formula containing 1.6 to 1.8 g of protein per 100 kcal should be clinically evaluated by a national and/or regional authority. Based on the conclusions of the EFSA Scientific Opinion and the views of the eWG, it is recommended that a minimum protein level of 1.6 g/100 kcal is established and that clinical evaluation is required for formula with protein levels below 1.8 g/ 100 kcal. This drafting still enables countries to consider whether to permit protein levels below 1.8 g/ 100 kcal based on their own clinical evaluation of the evidence and the nutritional needs of their local population.

Based on the conclusions of the EFSA Scientific Opinion and the responses from the eWG, it is recommended that a minimum protein level of 1.6 g/100 kcal is established for follow-up formula for older infants. The Chairs suggest that the minimum is presented in the table instead of in the footnote to align with the Infant Formula Standard and as is commonly done in Codex Standards.

It is also recommended that no amendments are made to the minimum protein requirements of formulae based on soy protein isolates or hydrolysed protein, as there is no new evidence available demonstrating safety and suitability of lower levels.

The Chairs recommend to combine the two sentences relating to the clinical evaluation of formula based on non-hydrolysed milk protein containing less than 1.8 g/protein/100 kcal and formula based on hydrolysed protein containing less than 2.25 g/protein/100 kcal in footnote 6. The Chairs note that this would align with the approach in the Infant Formula Standard.

In addition the Chairs propose to add the g/100 kJ equivalents to all footnotes and that these are rounded to two decimals consistently.

**Recommendation 1:**

That CCNFSDU agree to revise the protein requirements as follows:

1. that a minimum protein level of 1.6 g/100 kcal is established and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/ 100 kcal.
2. that the minimum protein value for soy protein isolate is retained, and that the second sentence in footnote 5 is amended to be consistent with the first (include 'or goats').
3. that the current minimum for follow-up formula based on hydrolysed protein is retained.
4. that the two sentences relating to the clinical evaluation of formula based on non-hydrolysed milk protein containing less than 1.8 g /protein/100 kcal and formula based on hydrolysed protein containing less than 2.25 g/protein/100kcal in footnote 6 are combined.

**a) Protein** <sup>2), 3), 4)</sup>

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.6] <sup>5),6)</sup>	3.0	-
g/100 kJ	[0.38] <sup>5),6)</sup>	0.72	-

<sup>2)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>3)</sup> For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

<sup>4)</sup> Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

<sup>5)</sup> The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' **[or non-goats']** milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of **[2.25 g/100 kcal (0.54 g/100 kJ)]** applies.

~~<sup>6)</sup> Follow-up formula based on non-hydrolysed milk protein containing [1.61 — 1.8 g] protein/100 kcal should be clinically evaluated by a competent national and/or regional authority. Follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated.~~

<sup>6)</sup> Follow-up formula based on non-hydrolysed milk protein containing **[less than 1.8 g] protein/100 kcal [(0.43 g/100 kJ)]** and follow-up formula based on hydrolysed protein containing less than {2.25 g protein/100 kcal} **(0.54 g/100 kJ)** should be clinically evaluated by a competent national and/or regional authority.}

## 1.6 Optional addition: Docosaehaenoic acid

### 1.6.1 Background

In 2015, CCNFSDU37 wished to further consider establishing a minimum level to guide the voluntary addition of DHA for the purposes of ensuring that the product contains sufficient amounts to achieve the intended effect ([REP16/NFSDU](#) para 58(d)). The purpose of which was to assist national and/or regional authorities when considering Principle 3.2.2 for the optional addition of ingredients:

3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.

FAO has recommended adequate intakes of long chain polyunsaturated fats of between 0.2-0.36% of total fatty acids (approx. 10-20 mg, FAO 2010); whereas EFSA has concluded that 100 mg of DHA per day is adequate for the majority of infants (EFSA 2014).

The statements in the footnote relating to levels of arachidonic acid (20:4 n-6) and eicosapentaenoic acid (20:5 n-3) were agreed to during the CCNFSDU37.

#### **Minimum DHA content**

During the 2016 eWG and during CCNFSDU38 the minimum DHA level that was discussed was 0.3% of total fatty acids. A conversion of 0.3% fatty acids to 20 mg/100 kcal was suggested during CCNFSDU38 for the eWG to further consider. The value suggested at CCNFSDU38 to set a minimum value of 20 mg/100 kcal is based on approximately 0.36% fatty acids (rounded) and is the mandatory minimum level used in the European Union (EU 2016).

At CCNFSDU38, the Committee agreed to set a minimum content in a footnote relating to the addition of DHA as an optional ingredient, and to further consider the levels of DHA based on total energy density (e.g. mg/100 kcal) instead of as a percentage of total fatty acids ([REP17/NFSDU](#), para 58).

### **Guidance Upper Level DHA content**

A guiding upper level (GUL) of 0.5% total fatty acids was agreed to during the CCNFSDU37. The Committee accepted the recommendation that the GUL for the optional addition of DHA should align with that specified in the Infant Formula Standard. In the 2016 physical working group report ([CRD 2](#)) it was noted that many Codex Members did not consider that there was sufficient justification to vary from the Infant Formula Standard.

#### **1.6.2 Conversion of % fatty acids**

At the CCNFSDU38 the eWG was directed to further consider the levels of DHA based on total energy density (e.g. mg/100 kcal) instead of as a percentage of total fatty acids. Conversion of DHA values from percentage fatty acids to absolute values align with the requirements for other fatty acid specifications (i.e. linoleic acid and  $\alpha$ -linolenic acid). It also clarifies the appropriate minimum and guiding upper levels for follow-up formula for older infants and ensures that the levels are appropriate for product for young children where no maximum fat levels will be established and minimum levels have yet to be agreed on (see Section 3.4 outlining the recommendation to set a minimum fat level of 3.5g /100 kcal for product for young children).

The current draft standard states the following with regards to DHA requirements in follow-up formula for older infants:

<b>Docosahexanoic acid</b> <sup>20)</sup>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 kcal	-	-	<b>[To be fixed after the fat content has been agreed upon]</b>
mg/100 kJ	-	-	
<sup>20)</sup> If docosahexanoic acid (22:6n-3) is added to follow-up formula, a minimum level of <b>[20 mg/100 kcal]</b> should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexanoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.			

In order to convert the requirements as percentage of total fatty acids to absolute values they must be applied to the requirements specified for the fat composition of follow-up formula for older infants.

The Chairs calculated the conversion of the DHA levels from percentage total fatty acids to an absolute value based on energy density (e.g mg/100 kcal) in Table 7 and presented two options in the Consultation Paper. The Chairs note and apologise for a mistake in the Consultation Paper in the calculation converting the agreed GUL of 0.5% of total fatty acids using the maximum fat level of 6.0g. This should be 30 mg/ 100 kcal and not 33 mg/ 100 kcal.

**Table 7:** Conversion of percentage fatty acid requirements to absolute DHA requirements

<b>Fat composition of follow-up formula for older infants</b>	<b>DHA level</b>	
	<b>0.3% of total fatty acids</b>	<b>0.5% of total fatty acids</b>
Minimum fat: 4.4 g/100 kcal	13 mg/100 kcal 3.1 mg/100 kJ	22 mg/100 kcal 5.3 mg/100 kJ
Maximum fat: 6.0 g/100 kcal	18 mg/100 kcal 4.3 mg/100 kJ	30 mg/100 kcal 7.9 mg/100 kJ
Mid-point of the range: 5.2 g/100 kcal	16 mg/100 kcal 3.8 mg/100 kJ	26 mg/100 kcal 6.2 mg/100 kJ

The following two approaches were suggested in the Consultation Paper for the eWG to consider in establishing the requirements for DHA based on energy density (Table 8):

1. Enable the widest range of DHA levels within the 0.3-0.5% total fatty acid range
2. Application of the percentage fatty acid (0.3 – 0.5% total fatty acid) to the mid-point of the range of permitted fat levels.

**Table 8:** Options for consideration (as presented in the Consultation Paper for the 2017 eWG)

	DHA level	
	0.3% of total fatty acids	0.5% of total fatty acids
Option 1: widest range	13 mg/100 kcal 3.1 mg/100 kJ	30 mg/100 kcal 7.9 mg/100 kJ
Option 2: mid-point	16 mg/100 kcal 3.8 mg/100 kJ	26 mg/100 kcal 6.2 mg/100 kJ

*Option 1*

Under this option, it was proposed that the minimum DHA as percentage fatty acid (0.3% fatty acids) is applied to the minimum fat level (4.4 g/100 kcal) in the standard and the GUL (0.5% fatty acids) is applied to the maximum fat level (6.0 g/100 kcal). This approach would allow for the widest range of DHA levels proposed through the establishment of a minimum level in footnote 20. The GUL would also align with the maximum that is currently permitted in the Infant Formula Standard which is expressed as a percentage of fatty acids. This approach would result in a DHA minimum of 13 mg/100 kcal and GUL of 30mg/100 kcal.

*Option 2*

The second approach is that the conversion of percentage fatty acids are based on the midpoint of the total fat range (5.2 g/100 kcal). This approach would ensure that the minimum and GUL are based on the same underlying fat requirement level, but would result in a narrower range of DHA to be added. This approach would result in a DHA minimum of 16 mg/100 kcal and GUL of 26 mg/100 kcal.

**eWG views**

The eWG had diverging views on what the minimum and GUL for the voluntary addition of DHA should be when presented as energy density (mg/100 kcal).

In total eleven eWG members (10 CM, 1 CO) supported Option 1 for establishing a minimum and GUL for the optional addition of DHA by using the minimum and the maximum level of fat giving the widest possible range for the voluntary addition of DHA (13 mg /100 kcal to 30 mg/ 100 kcal).

Five member countries were in favour of Option 2 where the mid-point of the fat range is used to convert the percentage values to energy density. This would see a minimum of 16 mg/100 kcal and GUL of 26 mg/100 kcal. Reasons given were that this option gives a higher minimum level than option 1 and makes a more meaningful contribution to DHA intake.

Two member countries were of the view that no minimum should be set for an optional ingredient. Further one CO considered that setting a minimum for the addition of DHA should be left to national authorities and one CM did not support the voluntary addition of DHA to follow-up formula for older infants. In addition one CM suggested that a minimum of 0.2% of fatty acids could be considered as the minimum.

In total nine eWG members (5 CM, 1 CMO, 3 CO) were of the view that the minimum should be 20 mg/100 kcal and four were of the view that GUL should be set at 50 mg/100 kcal. Many referred to the minimum amount 20mg / 100 kcal mandated by the EU (EU 2016) and adequate intake level of 100 mg set by EFSA (EFSA 2014) as well as Section 3.2.2. of the draft standard for Follow-up Formula for the optional addition of ingredients that ingredients should be present at levels that is significant for infants. Several members commented that Option 1 (minimum 13 mg/ 100 kcal) would not be enough to provide an adequate amount of DHA for older infants. Whilst the members considered that this would be possible at the higher end of the proposed range in Option 1, it was noted that manufacturers should not be required to formulate products close to the GUL and that on the other hand the likelihood that manufacturers will formulate a product to contain anything greater than the minimum required is highly unlikely.

A number of eWG members provided the argument that the average intake of DHA from follow-up formula for older infants formulated using 13 mg DHA/100 kcal is not adequate to provide a meaningful contribution to the DHA requirements of older infants. It was mentioned that 13 mg DHA/100 kcal can be expected to supply an estimated 43-49 mg DHA/ day, which falls short of the adequate intake level set by EFSA (100 mg/day) and that complementary foods consumed by older infants are not expected to fill the remaining DHA intake gap (Forsyth et al. 2016) considering the availability of DHA in common complementary foods.

A suggestion was made to simplify the footnote:

*<sup>20)</sup> If docosahexaenoic acid (22:6n-3) (DHA) is optionally added to follow-up formula, the minimum content should be [13 mg/100 kcal (3.1 mg/100 kJ)]. Arachidonic acid (20:4 n-6) content should be at least the same as, and eicosapentaenoic acid (20:5 n-3) content should not exceed, the DHA content. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their local population.*

## Conclusion

The Chairs note the divergent views of the eWG members. However, the Chairs also note that a GUL of 0.5% of total fatty acids was agreed to in 2015, when the Committee accepted the recommendation that the GUL for the optional addition of DHA should align with that specified in the Infant Formula Standard. This results in a maximum GUL of 30 mg /100 kcal when converting the agreed percentage value to mg/100 kcal using the maximum level of fat agreed to for follow-up formula for older infants. Given that the maximum total fat for follow-up formula for older infants is also aligned with that in the Infant Formula Standard, the maximum level for addition of DHA is also 30 mg/100kcal in the Infant Formula Standard although it is expressed as a percentage of total fatty acids.

Taking into consideration the support from the eWG for converting the agreed GUL of 0.5% of total fatty acids using the maximum total fat for follow-up formula for older infants, it is recommended that 30 mg / 100 kcal is adopted as the GUL for the optional addition of DHA.

The support from the eWG for a minimum value of 16 or 20 mg/100 kcal is noted. However, it is recommended that 13 mg/100 kcal is adopted as the minimum for the voluntary addition of DHA as that gives the widest range for addition also noting that the footnote allows competent national and/or regional authorities to deviate from the conditions, as appropriate for their local population.

The Chairs recommend that the equivalent mg/100kJ values are also added.

It is noteworthy that it is not customary to include a minimum for an optional ingredient in Codex Standards.

### Recommendation 2:

That CCNFSDU agree:

that the minimum in the footnote for the optional addition of docosahexaenoic acid is set to 13 mg/100kcal (3.1 mg/100 kJ).

that the agreed GUL of 0.5% of total fatty acids is converted to 30 mg/100 kcal (7.9 mg/100 kJ).

#### Docosahexanoic acid <sup>20)</sup>

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	[30]
mg/100 kJ	-	-	[7.9]

<sup>20)</sup> If docosahexanoic acid (22:6n-3) is added to follow-up formula, a minimum level of [13 mg/100 kcal (3.1 mg/ 100 kJ)] should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as docosahexanoic acid. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexanoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their local population.

## 2 ESSENTIAL COMPOSITION OF [NAME OF PRODUCT] FOR YOUNG CHILDREN (12-36 MONTHS)

The focus of the Consultation Paper on Essential Composition: [Name of Product] for Young Children was to consider the outstanding compositional aspects of the Standard for Follow-up Formula for the age group 12-36 months.

Thirty five responses were received to the Consultation Paper:

27 Codex Member Countries (CM)

1 Codex Member Organisation (CMO) – representing 28 Member States

7 Codex Observers (CO)

### 2.1 Overview

#### 2.1.1 Terms of reference

At CCNFSDU38 (REP17/NFSDU, Appendix IV) the Committee agreed to the following term of reference specific to the Essential Composition of product for young children:

- To finalise the outstanding requirements for the Essential Composition of product for young children (12-36 months) (Sub-Section 3 of Section B).

The following requirements for the essential composition of product for young children remain in square brackets:

- Minimum total fat level
- Maximum available carbohydrates and associated sugar specifications in footnote 4
- Whether a calcium-to-phosphorous ratio should be established
- Vitamin D minimum and maximum levels (noting that a final decision is to be taken to make vitamin D addition mandatory)

### 2.1.2 Principles for the Essential Composition of Product for Young Children

At CCNFSDU38, it was agreed that the requirements for the essential composition of product for young children (12 – 36 months) are to be based on a narrow set of mandatory requirements, with the option that national authorities may require additional mandatory nutrients based on the nutritional needs of their population. The approach to be taken was informed by the agreement of the Committee in 2015 that the standard needed to be (REP 17/NFSDU, para 70):

- Flexible in composition;
- Less prescriptive, as product for young children does not need to contain the full range of nutrients that are mandated for addition to follow-up formula for older infants;
- Consistent with compositional parameters for follow-up formula for older infants (where possible); contain the key nutrients of global concern in the diets of young children, and the key nutrients in cows' milk, as well as maintain nutritional integrity.

This approach was elaborated in the 2016 eWG which developed principles to underpin the selection of nutrients for the mandatory essential composition of product for young children. At CCNFSDU38 the principles for selecting which nutrients must be mandatory were amended as follows.

Evidence to support:

1. Contribution to the nutritional needs of young children where the nutrient is widely inadequate; and/or
2. Contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or
3. The nutritional quality and integrity of product to ensure nutritional safety.

The Committee noted that breast milk, formulas for infants and cows' milk are all suitable for the young child age group, and as such any levels specified in the standard would need to accommodate these foods.

The Chairs have included these principles as an Annex to the draft revised standard as per the approach taken in *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-181).

## 2.2 Energy contribution from macronutrients

At CCNFSDU38, significant discussion was held on the establishment of minimum and maximum levels for macronutrients. Discussions were held during the physical working group (pWG), a side session to the pWG, and also within the Committee, the outcomes of which were captured as [CRD 2](#), [CRD17](#) and in the CCNFSDU38 report ([REP 17/NFSDU](#), para 81).

The Committee agreed to the following regarding the establishment of minimum and maximum levels for macronutrients ([REP 17/NFSDU](#), para 81):

- i. Agreed to set a maximum level for available carbohydrate and minimum levels for protein and fat;
- ii. Agreed to set a minimum level for protein of 1.8 g/100 kcal;
- iii. Noted that maximum levels for available carbohydrate that were considered included values of 12, 12.5 and 14 g/100 kcal;
- iv. Agreed that no minimum level would be set for carbohydrate and no maximum levels for protein and fat;
- v. Noted that the information in [CRD17](#) could serve as a guide for further discussions on these levels with specific levels for maximum carbohydrate and minimum fat to be discussed at the next session of CCNFSDU.

## 2.3 Protein Quality

At CCNFSDU38 there was widespread support to establish protein quality requirements. The Representative from FAO informed the Committee that the DIAAS (Digestible Indispensable Amino Acid Score) was not yet ready for use, and that for an interim period, the PDCAAS (Protein Digestibility Corrected Amino Acid Score) should be used. In response to requests from the Committee for guidance on protein quality, the FAO stated that they would consider convening an expert consultation to provide guidance on the appropriate use of protein quality assessment methods for Codex, focusing on the use of the PDCAAS method.<sup>1</sup>

As an interim measure, the Committee agreed that the quality of protein shall not be less than 85% of that of casein and agreed to the following proposed text on methods to determine protein quality:

**Protein\*\*)**

\*\* ) The quality of protein shall not be less than 85% of that of casein.

The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.

## 2.4 Minimum total fat

At CCNFSDU38 the Committee agreed to set a minimum level for total fat for [name of product] for young children. This was based on the view that fat requirements are necessary to ensure the nutritional integrity and balance of product.

The working group proceeded to look at three minimum levels that could be appropriate:

- 4.4 g/100 kcal to align with the minimum set in the draft standard for follow-up formula for older infants
- 3.5 g/100 kcal to accommodate formulations based on reduced fat cows' milk
- 4.0 g/100 kcal to provide nutritional integrity and a more flexible lower fat option than that required for follow-up formula for older infants

A side session to the pWG which was held prior to CCNFSDU38 evaluated the feasibility of options proposed. The conclusions of the pWG side session were that a minimum level of 3.5 g/100 kcal would be required to accommodate reduced fat cows' milk. Further modelling was done using typical ingredients used in the production of formula and product for young children. The scenarios are described in detail in the Consultation Paper.

### eWG views

The Consultation Paper asked whether the eWG members support establishing a minimum level of 3.5 g of fat per 100 kcal.

The majority of the eWG members (22 CM, 1 CMO, 3 CO) supported establishing a minimum fat level of 3.5 g/100 kcal. This level is comparable with that in reduced fat (semi-skimmed) milk and allows young children to meet the dietary fat recommendations of WHO/FAO. It also allows for sufficient formulation flexibility.

Some eWG members (3 CM, 3 CO) supported a higher minimum fat level of 4.0 g/100 kcal. Reasons given were that reduced fat cows' milk is not recommended to children during the first three years of life and that higher fat is needed to support children's growth and development, the country's national recommendation, and that only a fat level of 4.0 g/100 kcal or higher would fit within the adequate intake levels of 35-40% energy established for young children by EFSA (EFSA 2010). In addition it was mentioned that a minimum of 4.0 g/100 kcal would be consistent with current commercial practices.

A comment was made in support of a minimum fat level of 4.4 g/100 kcal, as it aligns with the level for follow-up formula for older infants. Having a fat level lower than 4.4 g/100 kcal would require a higher level of protein to reach the required energy density since a maximum level for carbohydrates will be established. Concern was raised that the result could be a product with a higher protein level than cows' milk.

### Conclusion

Based on the majority support among the eWG, it is recommended that a minimum fat level of 3.5 g/100 kcal is set for [name of product] for young children. This level allows for young children to meet dietary recommendations, accommodates formulations based on reduced fat cows' milk and allows for a nutritionally balanced product.

### Recommendation 3:

That CCNFSDU agree to establish a minimum level for fat of 3.5 g /100 kcal (0.84 g/100 kJ).

<sup>1</sup> FAO will provide a report back on the expert consultation (6 – 9 November 2017)

## 2.5 Carbohydrate

### 2.5.1 Background

At the CCNFSDU38 the Committee agreed to establish a maximum level for available carbohydrates, and to consider values of 12, 12.5 and 14 g/100 kcal.

In the Infant Formula Standard the minimum and maximum levels are set for total carbohydrates and at the CCNFSDU37 the Committee agreed to amend the title of 'total carbohydrates' to refer to 'available carbohydrates' when setting the minimum and maximum levels for older infants, to take into account that the levels indicated referred to digested and absorbed carbohydrates. Non digestible carbohydrates and dietary fibre are not included in the definition of available carbohydrates and their addition is captured under the Optional Ingredients section.

The Infant Formula Standard and revised requirements for follow-up formula for older infants, as agreed at CCNFSDU37, require that products contain 9-14 g/100 kcal available carbohydrate. These carbohydrate requirements are based on the residual energy in formula that contain the permitted minimum and maximum amounts of protein and fat.

Within the *Guidelines on Nutrition Labelling* it is required that where nutrient declaration is applied, the available carbohydrates (i.e. dietary carbohydrate, excluding dietary fibre) and total sugars are declared (3.2.1.2; [CAC/GL 2-1985](#)). The following definitions from these Guidelines are relevant for calculating the available carbohydrate content of food:

2.7 *Sugars* means all mono-saccharides and di-saccharides present in food.

2.8 *Dietary fibre* means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

It is noteworthy that the establishment of a maximum carbohydrate limit for [name of product] for young children results in formulations of product which could be low fat or low protein (i.e. the lowest levels under consideration) but not both, as the energy density requirements must still be fulfilled (60 – 70 kcal/100 mL).

It was recognised in the 2016 eWG and CCNSDU38 pWG that limiting the amount of available carbohydrates will also ensure that other glycaemic carbohydrates which may have similar metabolic effects to sugar are also limited in their addition. See section 3.6 for further discussion.

### 2.5.2 Maximum level available carbohydrate

#### eWG views

The Consultation Paper asked whether eWG members support establishing a maximum level of 12.5 g of available carbohydrate per 100 kcal and whether there are any additional issues that need to be considered.

The eWG views were mixed regarding what the maximum level for available carbohydrate should be.

There was substantial support for the proposal to set a maximum of 12.5 g/100 kcal (11 CM, 2 CO) and some eWG members supported a lower level of 12 g/100 kcal (1 CMO, 2 CM, 1 CO) or even lower 10 g/100 kcal (1 CM). On the other hand there was also considerable support to set the maximum at 14 g/kcal (13 CM, 2 CO) or even at 15 g/100kcal (1 CO).

Those that supported a level of 14 g/100kcal or higher did not consider there to be scientific substantiation to set a lower level and noted that this level aligns with the recommendation made by the Early Nutrition Academy (Suthutvoravut et al, 2015). At this level the maximum energy from carbohydrates equates to 56% of energy which is well within the recommendations from WHO (Mann J et al 2007), Institute of Medicine (IoM 2002), and EFSA (2013). A maximum level of 14 g/100 kcal of available carbohydrate also enables the greatest number of variations in formulation of product for young children and can accommodate products with lower levels of fat and protein. It was considered that there are no health risks associated with a maximum of 14 g/100 kcal and several members noted that this level also aligns with the level set for older infants and in the Infant Formula Standard.



Some eWG members supporting a maximum level of 14 g/100 kcal were of the view that if a maximum level of carbohydrates is set at 12.5 g/100kcal, the product will be driven towards higher protein or fat levels so the minimum levels established for protein and fat are no longer relevant. It was argued that there is no need to lower the maximum level for carbohydrates to 12.5 g/100 kcal since a limit on sugars [and other carbohydrates contributing to the sweet taste] is also proposed.

The eWG members of the view that a maximum level of 12.5 or 12 g/100 kcal should be established indicated that these values are closer to the amount of carbohydrates in breastmilk (9.6 g /100 kcal) and cow's milk (full fat 7.3 – 7.8 g/100 kcal, reduced fat 9.6-10.5 g/100 kcal) than a higher level of 14 g/100 kcal. This was also the argument provided by the member country that supported a maximum level of available carbohydrates no higher than 10 g/100 kcal. The eWG members in favour of a maximum level of 12.5 g/100 kcal considered that it allows for moderate levels of protein and fat, for greater flexibility in protein and fat formulations than a lower limit 12 g/100 kcal, and would result in a nutritionally balanced product.

Those in support of the 12.5 g/100 kcal or a lower level also stressed the importance of a lower limit for available carbohydrates to also partially limit the addition of free sugars and other carbohydrates contributing to the sweet taste in the product. However, in contrast to this, it was also mentioned that the limits for available carbohydrate and sugars should be assessed independently as limiting available carbohydrates does not address concerns on added sugars.

Despite the divergent views within the eWG regarding the maximum limit for available carbohydrates, there was general agreement among all eWG members that attention should be paid to restrictions on sugars and other sweet tasting carbohydrates.

### Conclusion

Based on the overall preference of the eWG for a maximum level of 12.5 g/100 kcal or lower (14 CM, 3 CO, 1 CMO – representing 28 member states) it is recommended that a maximum level of 12.5 g/100 kcal for product for young children is established.

#### Recommendation 4:

That CCNFSDU agree to establish a maximum level for available carbohydrates of 12.5 g/100 kcal (3.0 g/100 kJ).

## 2.6 Sugars, other than lactose, and other sweet tasting carbohydrates

### 2.6.1 Background

#### *Dietary guidelines*

In 2015, WHO strongly recommended that both adults and children reduce the intake of free sugars to less than 10% of total energy intake and conditionally recommended a further reduction to less than 5% of total energy intake (WHO 2015). Free sugars are defined by WHO as including “*monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates*”. Free sugars do not include intrinsic sugars and sugars naturally present in milk such as lactose because no reported evidence of adverse effects has been found.

As reported by the WHO and EFSA, there is increasing concern that intake of added/free sugars, particularly in the form of sugar-sweetened beverages, increase overall energy intake and may reduce the intake of foods containing more nutritionally adequate calories (WHO 2015, EFSA 2010b). The WHO recommendations are based on the effect of a reduction in free sugars on body weight and dental caries in both adults and children (WHO 2015). As noted in the report of the European Commission on young child formula, the role of sugars in obesity development and their impact on flavour development affecting taste preferences should be kept in mind (EU 2016b).

Based on this evidence the Committee was supportive at CCNFSDU38 of establishing limits on the addition of sugars other than lactose to product for young children. However agreement could not be reached on whether this should be set at either a maximum of 10% or 20% of the value for available carbohydrate, nor could agreement be reached on the text as to the types of carbohydrates to which the limit applies.

### 2.6.2 Restrictions in the footnote

The current drafting of the footnote related to carbohydrate for [name of product] for young children is:

*4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Sugars, other than lactose [or other carbohydrates contributing to the sweet taste of [name of product]] should not exceed [10%] or [20%] of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.*

The current agreed drafting of the footnote related to carbohydrates for [name of product] for young children states that lactose should be the preferred carbohydrate in [name of product] based on milk protein. In addition it has been agreed that sucrose and/or fructose should not be added, unless needed as a carbohydrate source. The 2017 eWG had to consider whether the limit for sugars other than lactose should be set at 10% or 20% of available carbohydrates and whether the limit should be extended to include other carbohydrates contributing to the sweet taste of the product. This was discussed in the Consultation Paper and eWG members were asked for their view on this (see below).

The footnote associated with carbohydrate in the Infant Formula Standard does not include a limit for sugars other than lactose. It does however state that sucrose should not be added unless needed, and that fructose should not be added. Lactose and glucose polymers (which would include maltodextrins and glucose syrups) are mentioned to be the preferred carbohydrates.

Infant Formula Standard Section 3.1.3 c) Footnote 9 reads:

*9) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added to Infant Formula up to 30% of total carbohydrates and up to 2 g/100 ml.*

*Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance.*

The draft text of the footnote related to carbohydrates that the Committee has agreed on for follow-up formula for older infants also lists lactose and glucose polymers as the preferred carbohydrates and includes 20% limit of available carbohydrates for sucrose and fructose combined. There is no limit for other sugars.

Agreed draft text of the footnote related to carbohydrates for follow-up formula for older infants:

*9) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.*

As noted by some within the 2016 eWG, limits applied only to total sugars (defined as mono- and disaccharides) will not limit the addition of other glycaemic carbohydrates such as malto-oligosaccharides (i.e. maltodextrin) and polysaccharides (e.g glucose polymers and starches). These carbohydrates are widely used in formulae and are not regarded as sugars within Codex or by some regulatory authorities. However, as they are glycaemic carbohydrates, the addition of these will be limited within the limit for available carbohydrates. Although many 2016 eWG members were concerned with the addition of excessive maltodextrins (particularly lower chain length maltodextrins), it was also stated that these should continue to be permitted as a source of carbohydrate. In the 2016 eWG it was not considered necessary to include a list of permitted types of carbohydrates within the standard as this would be inconsistent with the principle of flexibility.

### **Definitions of sugars**

As per the definition in the *Guidelines on Nutrition Labelling* ([CAC/GL 2-1985](#)), sugars are defined as mono- and disaccharides. The definition of 'free sugars' in the WHO recommendation is wider than the Codex definition, as it includes "monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates". It is also highlighted that the Standard for Sugars (CODEX [STAN 212-1999](#)) refers to various ingredient forms for sugar, including lactose, fructose, dextrose and glucose syrups, as these are the commodities that are traded.

### **Specifications for sugars, other than lactose, and other carbohydrates in EU legislation and ENA recommendations**

The revised EU regulation for follow-up formula for older infants contains specifications for the addition of sucrose, fructose and honey, glucose and glucose syrup (EU 2016). A maximum limit has been set for the addition of sucrose, fructose and honey of 20% of the total carbohydrate content, either separately or combined (EU 2016). If honey is used it is a requirement that this shall be treated to destroy spores of *Clostridium botulinum*. Regarding glucose addition, this can only be added to follow-up formula manufactured from protein hydrolysates, and if added cannot exceed 2 g/100 kcal. Glucose syrup is permitted to be added to follow-up formula if its dextrose equivalents do not exceed 32, and the addition does not exceed 0.84 g/100 kcal. Products for young children fall outside of the scope of this regulation as they are considered to be regular foods. EFSA has noted (EFSA 2014) that formula consumed during the first year of life can continue to be used by young children and therefore did not consider it necessary to propose specific compositional criteria for products for young children.

The international expert working group coordinated by the Early Nutrition Academy (ENA) to provide recommendations on the composition of formulas for young children (aged 1-3 years) recommended the following to guide addition of sugars other than lactose for products for young children: *there is no need to add sugars other than lactose for nutritional reasons. If sugar is deemed necessary to achieve palatability, the content of sugars other than lactose should not exceed 10% of total (available) carbohydrates or approximately 5% of total energy content* (Suthutvoravut et al 2015). With regards to other carbohydrates (non-sugars) the group stated that: *Other carbohydrates may be added provided maximum carbohydrate content is not exceeded. Oligosaccharides, glucose polymers, maltodextrin, and pre-cooked or gelatinized starches can be added to provide energy. Non-digestible carbohydrates and fibres that are proven to be suitable for age and safe may be added.*

### **Definition of 'sweet tasting carbohydrate'**

At the CCNFSDU38 it was suggested that 'other carbohydrates contributing to the sweet taste' should also be limited in addition to limiting the addition of sugars other than lactose. It was however acknowledged that 'other carbohydrates contributing to the sweet taste' is not a defined term and it can be interpreted in many ways. Dextrose equivalent (DE) limit was proposed as an option for defining 'other carbohydrates contributing to the sweet taste'. As noted above, the EU regulation for follow-up formula for older infants (EU 2016) contains a specification that glucose syrup is permitted to be added if its DE do not exceed 32, and the addition does not exceed 0.84 g/100 kcal.

A definition of DE is (Bender DA, 2009):

*"A term used to indicate the degree of hydrolysis of starch into glucose in corn syrup (see syrup, corn). It is the percentage of the total solids that have been converted to reducing sugars: the higher the DE, the more sugars and less dextrans are present.*

*Liquid glucoses are commercially available ranging from 2 DE to 65 DE. A complete acid hydrolysis converts all the starch into glucose but produces bitter degradation products. Glucose syrups above 55 DE are termed 'high conversion' (of starch); of 35–55 DE, regular conversion; below 20 DE the products of hydrolysis are maltins or maltodextrins."*

As per the definition above, the higher the DE, the more sugars which make the glucose syrup taste sweet, although less sweet than sucrose or fructose.

In the *Standard for Sugars* (CODEX [STAN 212-1999](#)) dextrose equivalent forms part of the definition for glucose syrup:

*A purified concentrated aqueous solution of nutritive saccharides obtained from starch and/or inulin. Glucose syrup has a dextrose equivalent content of not less than 20.0% m/m (expressed as D-glucose on a dry basis), and a total solids content of not less than 70.0% m/m.*

### **Summary of background**

The WHO recommendation for limiting free sugars to no more than 10% of total energy intake is based on strong science on the effect of a reduction in intake of free sugars on body weight and dental caries in both adults and children (WHO 2015). The proposed restrictions in the draft footnote related to carbohydrates for [name of product] for young children are consistent with the evidence supporting the WHO recommendation.

Although the *Guidelines on Nutrition Labelling (CAC/GL 2-185)*, define sugars as mono- and disaccharides, the WHO definition of 'free sugars' is wider than that and the EU regulation for follow-up formula for older infants sets limits for honey and glucose syrups in addition to sucrose, fructose and glucose. Whilst mono- and disaccharides are the sweetest carbohydrates, there are other carbohydrates used in the production of young child formula that could contribute to the sweet taste. It is acknowledged that defining these carbohydrates can be difficult. The Chairs of the eWG note that one way of addressing this is the approach taken by the EU by setting a maximum DE for glucose syrups of 32. It is also noted that establishing a maximum limit on available carbohydrates will inherently restrict the addition of carbohydrates which may contribute to a sweet taste.

### **eWG views**

The Consultation Paper provided two different percentage limits to be applied to either 'sugars other than lactose' or 'sugars other than lactose and other carbohydrates contributing to the sweet taste' of the product resulting in total four different options for the eWG to consider.

The options presented in the Consultation Paper and the support for them from the eWG members were as follows:

- 20% of available carbohydrates applicable only to sugars other than lactose (12 CM, 2 CO)
- 20% of available carbohydrates applicable to sugars other than lactose, and other carbohydrates contributing to the sweet taste (2 CM)
- 10% of available carbohydrates applicable only to sugars other than lactose (4 CM)
- 10% of available carbohydrates applicable to sugars other than lactose, and other carbohydrates contributing to the sweet taste (1 CMO, 7 CM, 1 CO)

In addition some eWG members commented that they did not find any of the above options acceptable.

Those eWG members supporting a 20% limit applicable only to sugars other than lactose mentioned that they considered it to be in line with the WHO recommendation that no more than 10% of total energy intake should come from free sugars. Together with a maximum established for available carbohydrates, it was considered to adequately address the health issues around sugar consumption and the sweet taste of the products. Some eWG members that supported the limit of 20% for sugars other than lactose had a preference for expressing the limit as 10% total energy, in line with the language of the WHO recommendation.

It was also argued that there are carbohydrates that are from a chemical point of view sugars (mono- or disaccharides), but are different from a physiological point of view and having a strict restriction would limit their use. An example given of such a carbohydrate is the disaccharide isomaltulose, which, as being slowly but fully digestible/available results in low-glycaemic properties comparable to lactose. It was mentioned that at the same time, isomaltulose is not used for its sweetness (it is less than half as sweet as sucrose) but as a slow release carbohydrate source in the product. Therefore a strict limit for sugars other than lactose would limit the use of such carbohydrates as well.

Two Codex Observer organisations mentioned in their comments that malto-oligosaccharides (i.e. maltodextrin) or polysaccharides (e.g. glucose polymers and starches) are not sweet tasting carbohydrates unlike what the Consultation Paper on Essential Composition of product for Young Children mentioned (Background section 3.1), and they are not added to the products for young children for their sweetening properties since their relative sweetness compared to sucrose is low.

Those supporting a 10% limit applicable to sugars other than lactose, and other carbohydrates contributing to the sweet taste, stressed the importance of the development of taste preferences in early childhood and considered that limiting sugars other than lactose would not be sufficient. A comment was made that in addition to limiting sugars, limiting carbohydrates that contribute to the sweet taste of [name of product] for young children was important as some products, such as low lactose or lactose free products, could contain predominantly polysaccharides, with a sweetness level comparable to the sweetness level of glucose and lead to products with a distinctive sweet taste.

Those supporting a 10% limit noted that having a maximum limit for available carbohydrate content to up to 12 g or 12.5 g/100 kcal and a limit for sugars other than lactose could still lead to products with a distinctive sweet taste which in turn could potentially negatively influence the development of taste preferences of young children. As there are different polysaccharides available that do not provide a sweet taste that can be used as a carbohydrate source for formulations that are lactose-free or contain low levels of lactose, it was mentioned that these should be preferred.

### 2.6.3 Additional views on how to limit addition of 'other sweet tasting carbohydrates'

The Consultation Paper also asked the eWG members for their views on how the excessive addition of carbohydrates contributing to the sweet taste should be limited, if they did not support the extension of the percentage limit for sugars to other carbohydrates.

#### eWG views

Eighteen eWG members (16 CM, 2 CO) preferred an option with a limit (either 10% or 20%) for sugars other than lactose only. On the other hand eleven eWG members (9 CM, 1 CMO, 1 CO) preferred an option with a limit including other carbohydrates contributing to sweet taste. It was noted that the term 'other carbohydrates contributing to the sweet taste' is unclear and open to interpretation. Should it be used, it would need to be clearly defined in the Standard.

Some eWG members expressed their view that an appropriate carbohydrate profile of the product would already be ensured by limiting added sugars other than lactose to a maximum of 20% available carbohydrates (equal to 10% of total energy of the product), and that since lactose will be the preferred carbohydrate no further considerations are needed for other carbohydrates.

Further two member countries were of the view that the following would be adequate and limit excess added sugars and other refined carbohydrates:

- 1) a maximum limit for available carbohydrates,
- 2) a specified limit on the contribution of added sugars other than lactose,
- 3) and the guidance that lactose should be the preferred carbohydrate

A comment was also made that the perception of sweetness is highly subjective and can vary in different regions of the world, which is why the limitation of addition of carbohydrates contributing to the sweet taste (other than sugars) should be left to national authorities.

Another comment was made that the Infant Formula Standard has a footnote which in addition to lactose also includes glucose polymers as the preferred carbohydrates so there should be no reason to limit them in product for young children beyond the maximum limit for available carbohydrates. The agreed footnote for older infants also mentions lactose and glucose polymers as the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.

Further suggestions provided by eWG members for the footnote:

4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. **Added** Sugars, other than lactose [or other carbohydrates contributing to the sweet taste of [name of product] should not exceed **10% of total energy**. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

4) Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Added Sugars, other than lactose should not exceed 10% of total energy.

"Lactose should be the preferred carbohydrate in (name of the product) based on milk protein. Other carbohydrates sources that do not add sweetness may also be considered. Sugars other than lactose should not exceed [10% of total energy or 20 % of available carbohydrate]. Sucrose and /or fructose should not be added unless needed as a carbohydrate source".

#### ***Dairy vs plant-based products***

Two member countries supporting a limit of 10% applicable to sugars other than lactose and other carbohydrates contributing to the sweet taste, proposed that further consideration should be given to a different limit for plant based and/or lactose free products. In addition two Codex observer organisations considered that dairy and plant-based products would not be treated equally by establishing a limit for sugars other than lactose at the proposed levels of either 10% or 20% of available carbohydrates as according to them such levels do not allow a good tasting well accepted product for young children.

One Codex Observer organisation recommended that the condition of use for the claim 'low in sugars' in the EU health and nutrition claims regulation (1924/2006) that a product contains no more than 2.5 g sugars/100 ml is adopted to prevent discrimination against non-dairy or lactose free products.

#### **Conclusion**

Taking into account the eWG views and the strong support to align with the WHO recommendation that free sugars should contribute no more than 10% of total energy intake and acknowledging the importance to limit sugars in [name of product] for young children for future health and development of taste preferences, the Chairs recommend that a limit is set for mono- and disaccharides of 20% of available carbohydrates. Lactose is excluded from this restriction. Acknowledging the differences in definitions for 'sugars', it is the Chairs' view that this could be clarified by replacing 'sugars' with 'mono- and disaccharides'. The Chairs also propose that consideration is given to the inclusion of wording from the WHO (2015) recommendation that 'mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate'.

Given that there has been general agreement that [name of product] for young children should not be overly sweet tasting, this intent could also be captured in the footnote related to carbohydrates. This has not been discussed by the eWG. The Chairs could support the inclusion of a reference that other sweet tasting carbohydrates and/or ingredients should not be added.

The Chairs could also support that if a level of 20% of available carbohydrates is agreed to as is proposed in the Recommendation 5 below, the same limit is applied to all products, regardless of the source of the protein.

In addition to the restrictions in footnote 4, the maximum to be agreed to for available carbohydrates (see section 3.5.2), will also limit the use of 'other carbohydrates contributing to the sweet taste' in the product for young children.

The Chairs would also like to note the majority support in section 3.6.4 to convert percentage limits to an absolute amount based on energy density once agreement is reached on the maximum level for available carbohydrates.

#### **Recommendation 5:**

That CCNFSDU:

1. agree to establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates.
2. agree that sweet tasting carbohydrates are restricted in accordance with the amended footnote 4 below.
3. considers the need to limit the addition of non-carbohydrate ingredients with the purpose of imparting a sweet taste.

#### **Carbohydrates**

##### **Available carbohydrates<sup>4)</sup>**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100 kcal	-	[12.5]	-
g/100 kJ	-	[3.0]	-

<sup>4)</sup> Lactose should be the preferred carbohydrate in [name of product] based on milk protein. ~~Sugars, other than lactose for other carbohydrates contributing to the sweet taste of [name of product] should not exceed [10%] or [20%] of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.~~

**[Mono- and disaccharides]**, other than lactose, should not exceed 20% of available carbohydrate. **[Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.]** Sucrose and/or fructose **[and/or other carbohydrates contributing to the sweet taste of [name of product]]** should not be added, unless needed as a carbohydrate source. **[Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]**

#### **2.6.4 Conversion of % limits to an absolute amount based on the energy density**

The Chairs suggested in the Consultation Paper that once a decision is made on the maximum level of available carbohydrates that the percentage limit for sugars [and other carbohydrates contributing to the sweet taste] is converted to an absolute amount based on the energy density of product for young children (i.e. g/100 kcal and g/100 kJ). For those products that are formulated to contain lower carbohydrate levels this will ensure that the absolute amount of sugars (other than lactose) and, should they be included within the limit for sugars, other sweet tasting carbohydrates are limited across all products to the same extent and it will provide more clarity in the standard.

#### **eWG views**

There was majority support for this proposal with 24 eWG members agreeing with it (20 CM, 4 CO).

Four member countries preferred to present limits as percentage of total energy as this would be in line with the WHO recommendation. Additional three eWG members (1 CMO, 2 CM) preferred to present limits as a percentage of total available carbohydrates.

### Conclusion

Based on the majority support within the eWG it is recommended that the percentage limit for sugars [and other carbohydrates contributing to the sweet taste] is converted to an absolute amount based on the energy density of product for young children once a decision is made on the maximum level of available carbohydrates.

#### Recommendation 6:

That CCNFSDU agree that the percentage limit for sugars [and other carbohydrates contributing to the sweet taste] is converted to an absolute amount based on the energy density (g/ 100 kcal and g/ 100 kJ) of product for young children once a decision is made on the maximum level of available carbohydrates.

## 2.7 Calcium-to-phosphorous ratio

At CCNFSDU38 minimum and guiding upper levels were established for calcium, riboflavin and vitamin B12. The decision to mandate these nutrients was based on the principle that these three micronutrients are key nutrients in cows' milk. These nutrients provide a significant contribution to the dietary requirements of young children – providing over 70% of a young child's requirement in a 300 mL serve of cow's milk. In the 2016 eWG it was considered important that products which may substitute cows' milk provide sufficient quantities of these key nutrients and this was agreed to at the CCNFSDU38.

Some members of the 2016 eWG supported the establishment of a calcium-to-phosphorous ratio to ensure adequate mineral balance for the purposes of nutritional integrity. Whereas others in the Committee did not think that there was a need to establish a ratio as it did not fulfil any of the principles for addition. As the Committee could not come to a consensus at CCNFSDU38, it was agreed to continue the discussion within this years' eWG. The 2017 eWG was asked in the Consultation Paper to consider whether a ratio of specifying a minimum 1:1 and maximum 2:1 for calcium-to-phosphorous should be included for [name of product] for young children.

### eWG views

Thirteen member countries were of the view that a minimum 1:1 and maximum 2:1 calcium-to-phosphorous ratio should be included for [name of product] for young children. Similar to arguments in 2016, it was mentioned that given the mandatory addition of calcium, ratio it is important for ensuring an adequate mineral balance to support for example bone mineralization, and ratio aligns with the requirement for older infants.

It was also stated that other potential nutrient interactions between other minerals (e.g. magnesium, zinc, and iron) and relationships may also need to be considered to assure the nutrients are bioavailable to the young child from the product's matrix.

Seventeen eWG members (12 CM, 1 CMO, 4 CO) were of the view that there is no need to establish a calcium-to-phosphorous ratio. Arguments for this were that the product is a part of a mixed increasingly diversified diet providing phosphorous from other sources, phosphorous is not considered to be a key nutrient in cows' milk, WHO/FAO have not established a dietary intake reference value for phosphorous and there is no evidence for phosphorous intake being inadequate. Therefore it does not fulfil the principles of mandatory addition.

### Conclusion

Noting the mixed views of the eWG but based on the majority preference, it is proposed that no calcium-to-phosphorous ratio is included for [name of product] for young children as phosphorous does not fulfil the agreed principles of addition. The mandatory requirements for the composition of product for young children should take into account the need for flexibility and less prescription, only mandating requirements for those nutrients which meet the outlined principles for addition (see Section 3.1.2).

#### Recommendation 7:

That CCNFSDU agree that no calcium-to-phosphorous ratio is included for [name of product] for young children.

## 2.8 Vitamin D

At CCNFSDU38 there was insufficient time to discuss the 2016 pWG recommendation that vitamin D should be a mandatory nutrient added to product for young children ([NFSDU/38 CRD/2](#)). The pWG fully supported the inclusion of vitamin D as a mandatory nutrient as it met principle 1, that it is widely inadequate in the diets of young children. The approach taken for the establishment of minimum and maximum/guiding upper levels for all mandatory micronutrients for [name of product] for young children to date has been to align with the levels agreed to for follow-up formula for older infants and to accommodate the nutrient levels found intrinsically in cows' milk. Although it was agreed to add vitamin D, two proposals for minimum and maximum limits were proposed by pWG members and are in square brackets for the eWG's consideration.

The Consultation Paper put forward the two proposals for a minimum and maximum level for the addition of vitamin D for the eWG to consider.

The current drafting has vitamin D still in square brackets given that the Committee did not discuss the pWG's recommendation to make addition of vitamin D mandatory.

The current drafting:

<b>[Vitamin D]</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>[GUL]</b>
µg <sup>9)</sup> /100 kcal	[1.5] or [1.0]	[4.5] or [3.0]	-
µg <sup>9)</sup> /100 kJ	[0.36 ] or [0.24]	[1.08] or [0.72]	-

<sup>9)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

### eWG views on minimum level

Ten eWG members( 9 CM, 1 CMO) supported the lower minimum level of 1.0 µg /100 kcal to align with the Infant Formula Standard and older infants. Other reasons mentioned were that there are regional differences in vitamin D status and national supplementation programmes already in place in some countries to address vitamin D deficiency.

On the other hand 20 eWG members (16 CM, 4 CO) were of the view that 1.5 µg /100 kcal should be adopted as the minimum level given the significant level of vitamin D insufficiency in older infants and young children. Alignment with the Infant Formula Standard and older infants was not considered to be relevant for this age group. It was also mentioned by several members that the higher minimum is in line with recommendations by the International Expert Group coordinated by the Early Nutrition Academy (Suthutvoravut et al 2015)

### eWG views on maximum level

Maximum level of 3.0 µg /100 kcal was preferred by eight eWG members (7 CM, 1 CMO). This was mentioned to align with the maximum for vitamin D in follow-up formula for older infants and ensure consistency with the approach followed for the mandatory addition of other micronutrients whose intake are widely inadequate in young children.

Twenty eWG members (17 CM, 3 CO) supported a maximum vitamin D value of 4.5 µg /100 kcal. Like the higher of the proposed minimum values 1.5 µg /100 kcal, this was mentioned to be in line with the recommendations by the International Expert Group coordinated by the Early Nutrition Academy (Suthutvoravut et al 2015) and it was mentioned it would accommodate for the differences in needs of populations in different countries. This level was generally not considered to exceed the UL by IoM (IoM 2011), however one member country considered there might be a risk overdose at this level.

In addition one member country was of the view that no maximum level should be set due to vitamin D deficiency being a public health concern. Another member country considered both maximum levels to be very high compared to its national recommended dietary allowance.

### Conclusion

Although the Consultation Paper did not specifically ask the eWG members to state their view on whether the addition of vitamin D should be mandatory, many eWG members (8 CM, 1 CMO, 1 CO) commented that they support the mandatory addition of vitamin D which was the recommendation of the 2016 pWG.

Based on the majority view of the eWG, it is proposed to deviate from the approach to align with the levels agreed to for follow-up formula for older infants and recommended that the addition of vitamin D will be mandatory at a minimum level of 1.5 µg /100 kcal (0.36 µg /100 kJ) and a maximum level of 4.5 µg /100 kcal (1.08 µg /100 kJ).



**Recommendation 8:**

That CCNFSDU agree to the mandatory addition of vitamin D and minimum and maximum levels as follows:

**Vitamin D**

Unit	Minimum	Maximum	GUL
µg <sup>9)</sup> /100 kcal	[1.5]	[4.5]	-
µg <sup>9)</sup> /100 kJ	[0.36 ]	[1.08]	-

<sup>9)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

**3 PREAMBLE****3.1 Overview**

Prior to introducing the Scope of the Standard, members of the 2016 eWG suggested starting with a preamble statement to set the scene for the entire Standard and to add clarity. A format similar to that of the Infant Formula Standard would see the inclusion of a single preamble statement which clarifies that the Standard is divided into two parts, with a clear distinction in the naming of the two products. The Scope and Labelling sections can then be tailored as appropriate for the two categories of product; follow-up formula for older infants and [name of product] for young children.

In addition to considering a Preamble statement, the 2017 eWG were asked to consider if referencing relevant WHO documents and WHA resolutions is necessary within the Standard, and if so, should the reference sit in the Preamble to the Standard or within the Scope section. Whilst at CCNFSDU38 the Secretariat identified that the Scope should be a concise statement in accordance with the Procedural Manual, the Committee had a preference for following the structure of the Infant Formula Standard, which would see relevant WHO documents and WHA resolutions referenced in the Scope section (specifically provision 1.4), if the eWG determined that they should be referenced.

In response to questions raised in the 1<sup>st</sup> Consultation Paper relating to provision 1.4 of the Scope for both follow-up formula for older infants and [name of product] for young children, it was noted that within the 2017 eWG there were more respondents supporting reference to one or more WHO/WHA documents within the Follow-up Formula Standard than there were respondents against any form of reference (see Section 6.2.4 of this paper for a summary of eWG views). Strong positions were presented for and against referencing WHO/WHA documents and determination of which documents may be appropriate and applicable is proving to be challenging. Electronic working group views ranged from those who do not support the inclusion of any WHO/WHA documents in Codex Standards to those members who favour listing all WHO/WHA documents/resolutions that may in some part be applicable to infant and young child feeding.

There were very strong opinions from 2017 eWG members on this issue and it is not a case of gathering more data or information to help progress the decision. Therefore, to assist the eWG and Committee in progressing this issue, the Chairs requested guidance from the Codex Secretariat on managing what appears to be a wider policy consideration that could impact on other committees, standards and guidelines.

**3.2 Background**

In response to the Chairs' request for assistance on progressing the issue of referencing WHO documents and WHA resolutions within the Standard, the Secretariat worked with WHO to determine the best way forward.

By way of background, it is important to note that at the 11<sup>th</sup> Session of the Codex Alimentarius Commission (1976), it was proposed that the *Standard for Infant Formula*<sup>2</sup> should include a statement encouraging breastfeeding. In line with this discussion, the Commission agreed that, when issuing the Standard for acceptance by governments<sup>3</sup>, a preamble should be included by the Secretariat indicating the policy of FAO/WHO concerning infant nutrition, including a statement that, where possible, breastfeeding should be preferred ([ALINORM 76/44](#), paragraph 344).

<sup>2</sup> Predecessor of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981). Originally developed as a regional standard CAC/RS 72-1972 before being adopted as a worldwide standard in 1981 as CODEX STAN 72-1981.

<sup>3</sup> This acceptance procedure was discontinued in 2005 following the WTO agreements ([ALINORM 05/28/41](#), para. 30).

In response to this decision, and, to set the context / environment of the standards, the *Statement on Infant Feeding* was included as a preamble to the *Codex Standard for Foods for Infants and Young Children*, which then consisted of the *Standard for Infant Formula* (CODEX STAN 72-1981), *Standard for Canned Baby Foods* (CODEX STAN 73-1981) and the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981).<sup>4</sup> However, when these three standards were disassembled as they are currently, the preamble “*Statement on Infant Feeding*” became an independent document, [CAC/MISC 2-1976](#).

There is therefore agreement by Member States for including a preamble to Codex standards indicating the policies of FAO and/or WHO regarding infant and young child nutrition including that on breastfeeding in order to provide the context for the implementation of such standards.

### 3.3 Proposed approach

In light of this background, and after consultation and discussion with WHO, the Codex Secretariat is proposing that the agreement made at CAC11 in 1976 be implemented for the Standard for Follow-up Formula (and in the future also for other relevant standards) with the following wording including the specific references, noting that this approach to the preamble would replace the need to list or reference specific resolutions within different sections in the Standard itself as the preamble is applied to the Standard as a whole.

This proposed approach and the concept of a preamble as agreed by the Codex Secretariat and WHO is seen as a workable solution for progressing this issue. This approach would also make provision 1.4 of the Scope redundant for both follow-up formula for older infants and [name of product] for young children.

#### Recommendation 9:

- 1) That CCNFSDU agree to the approach proposed by the Codex Secretariat and WHO, that being to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA resolutions, noting this approach to the Preamble would replace the need to list or reference these documents and resolutions within different sections of the Standard itself.
- 2) That CCNFSDU agree to the following Preamble statement proposed by the Codex Secretariat and WHO, and select the preferred wording from that presented in square brackets:

*The Codex Alimentarius Commission acknowledges the need to [protect and support /recognize] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.*

*This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).*

## 4 SCOPE AND LABELLING

### 4.1 Overview

The 2017 eWG were tasked with reviewing the Scope and Labelling Sections of the Follow-up Formula Standard with a point of differentiation at 12 months, for Section A and Section B of the draft Standard based on the discussions at CCNFSDU38, and propose draft text.

<sup>4</sup> Previously contained in the Codex Alimentarius Volume IX – Codex standards for foods for special dietary uses including foods for infants and children and related code of hygienic practice – these Codex volumes were available until 2001 but discontinued since then.

The focus of the 1<sup>st</sup> Consultation Paper was to consider the Scope and Labelling aspects of the Standard for Follow-up Formula with a point of differentiation at 12 months, as well as a discussion of the name and definitions of the respective product categories.

The 1<sup>st</sup> Consultation Paper also provided an opportunity for eWG members to comment on the context and relevance of WHA resolutions and WHO documents, as well as their applicability to the Standard.

For the second round of consultation, two separate papers were prepared on the Scope, Labelling and Definition sections. These sections were considered separately for follow-up formula for older infants and then for [name of product] for young children. The purpose of this approach was to assist in differentiating the two products by considering the individual Scope and Labelling aspects separately for each of the two products. This process complemented the approach taken for the compositional requirements of the two products where there is a point of differentiation at 12 months as recommended by the Committee, which has acknowledged that the two products are distinctly different from one another.

This Agenda Paper presents recommendations for the Scope, Labelling and Definition sections for follow-up formula for older infants and [name of product] for young children based on the comments received from the 2017 eWG.

Whilst Appendix II presents the drafting of the revised Standard in two separate sections for the composition, scope and labelling aspects, the format of the final Standard and how these provisions for the respective products will be presented, has not yet been decided. Separate consideration and presentation of these provisions for the two product categories does not prejudice or determine the final structure of the Standard(s).

The title of the Standard will also be dependent on the final structure of the Standard and the final names of the products included in the Standard.

#### 4.2 Scope - Background

At CCNFSDU38 the Committee agreed that;

- i. the Scope from the [Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants](#) should be the starting point for this Standard;
- ii. the reference to relevant WHO guidelines and WHA resolutions could either be included in a preamble to the Standard or in the Scope; and
- iii. all remaining matters could be considered in the eWG (REP17/NFSDU, para 113).

During the Committee the Secretariat referred to the *Format for Codex Commodity Standards* (25<sup>th</sup> [Procedural Manual](#) (2016)) which indicates *'the statements which should be included in standards as appropriate under the relevant headings of the standard'*. In relation to the Scope, the Procedural Manual states that:

*This section should contain a clear, concise statement as to the food or foods to which the standard is applicable unless this is self-explanatory in the name of the standard. In the case of a general standard covering more than one specific product, it should be made clear as to which specific products the standard applies.*

As per (ii) above, the eWG was asked to consider if referencing relevant WHO documents and WHA resolutions is necessary within the Standard, and if so, should the reference sit in the Preamble to the Standard or within the Scope section.

#### 4.3 Labelling – Background

The 2017 eWG was charged with reviewing the Labelling section of the Standard with a point of differentiation at 12 months.

At CCNFSDU38 the Committee noted that the issue of whether follow-up formula should be considered a breast-milk substitute or not should be considered by the eWG. The Committee also requested that the eWG examine the promotional aspect of follow-up formula, as well as misleading claims.

In response to a question at CCNFSDU38 as to whether Codex standards extend to promotional practices, the Secretariat clarified that while Codex could deal with issues of advertising, it did not have specific guidelines for marketing (REP17/NFSDU, para 120).

It is worth noting that the Terms of Reference for the Codex Committee on Food Labelling (CCFL) are:

- (a) to draft provisions on labelling applicable to all foods;
- (b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines;

- (c) to study specific labelling problems assigned to it by the Commission; and
- (d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.

All labelling provisions for follow-up formula for older infants and [name of product] for young children will need to go to the CCFL for endorsement. Further to this, CCNFSDU could refer issues or specific questions related to advertising to the CCFL for consideration and endorsement if deemed necessary.

The current structure of the Labelling section within the Follow-up Formula Standard has been retained with some minor modifications to the titles. As the current Follow-up Formula Standard is outdated, the approach taken by the eWG was to use the content of the more recent Infant Formula Standard as the starting point for the review of the labelling provisions, aligning where possible and appropriate, and noting where labelling aspects of the current Follow-up Formula Standard may need to be included.

Section 9 of both the Codex Infant Formula and Follow-up Formula Standards have product specific provisions under the following sub-headings:

- 9. LABELLING
  - 9.1 The name of the ~~food~~ [product]
  - 9.2 List of ingredients
  - 9.3 Declaration of nutritive value
  - 9.4 Date marking and storage instructions
  - 9.5 Information for ~~utilization~~ [use]
  - 9.6 Additional [labelling] requirements

The different role in the diet of follow-up formula for older infants compared to that of [name of product] in the diet of young children has been acknowledged by previous eWG's, and as such the labelling provisions were considered separately for the two product categories (follow-up formula for older infants, and [name of product] for young children), in line with the approach taken for the compositional provisions.

At CCNFSDU37, the Committee made the decision to refer to 'product' rather than 'food' as part of definition, and therefore consequential changes throughout the text, including Section 9 – Labelling have been made.

Whilst the 2017 eWG was charged with reviewing the Labelling section of the Standard with a point of differentiation at 12 months, the format of how separate labelling provisions for the respective products will be presented has not yet been decided. As discussed at the CCNFSDU38, the Standard is being developed as Section A (follow-up formula for older infants), and Section B [name of product] for young children, until such a time that a decision can be made on the final structure of the Standard.

## 5 SCOPE AND LABELLING – OLDER INFANTS (6-12 MONTHS)

A total of 36 responses were received to the 2<sup>nd</sup> Consultation Paper on the Scope and Labelling of follow-up formula for older infants:

- 28 Codex Members (CM)
- 1 Codex Member Organisation (CMO) – representing 28 Member States
- 7 Codex Observers (CO)

With respect to the analysis of submissions, one CM submitted a response that supported the position of the CMO. To avoid their response being counted twice, their response was taken account of when considering the position of the CMO. This approach resulted in the tally of responses from CMs being reduced to 27.

### 5.1 Classification of Product

As per [REP17/NFSDU](#) (para 116), the 2017 eWG was asked to consider the issue of 'whether the products should be considered breast-milk substitutes'. This was considered by eWG members when answering questions relating to the Scope, in particular when giving consideration to; if and how, the Standard could take into account any WHA resolutions and WHO policies. Many eWG members also considered whether follow-up formula for older infants may be a breast-milk substitute as part of forming their position on additional labelling requirements and the definition of product.

As part of the consultation process, the eWG was asked if it is important for the Standard to classify follow-up formula as a breast-milk substitute, or not, when responding to questions on the Scope, Labelling provisions and Product Definition.

## 5.2 Scope – Individual Provisions

### 5.2.1 Scope – Section 1.1

It has been proposed that the product definition and the role of follow-up formula in the diet of older infants sit outside the Scope and be captured within Section 2.1 – Product Definition so as to avoid repetition. The following statement was therefore proposed for consideration by the 2017 eWG:

- 1.1** This section of the Standard [**Section A**] applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

Based on the comments received from eWG members a second option was presented to the group for consideration. The second option involves the inclusion of the statement; *It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)*.

#### eWG views

The eWG was split on its preference for including the statement *It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)* to Section 1.1 of the Scope for follow-up formula for older infants.

#### Conclusion

Noting that the Secretariat identified at CCNFSDU38 that the Scope should be a concise statement in accordance with the Procedural Manual, and considering the proposed approach to the Preamble which would see the inclusion of the statement *It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)* within the Preamble, it is proposed that CCNFSDU adopt a clear and concise statement as to the food or foods to which the standard is applicable for Section 1.1.

#### Recommendation 10:

That CCNFSDU agree to the following statement for Section 1.1:

- 1.1** This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

### 5.2.2 Scope – Section 1.2

In the 1<sup>st</sup> Consultation Paper, the following statement was proposed for Section 1.2. This proposal aligns with the same provision within the Infant Formula Standard:

- 1.2** This section of the Standard contains compositional, quality and safety requirements for Follow-up Formula for Older Infants.

Whilst there was majority support for this proposal it was suggested that in order to be comprehensive, the labelling provisions and methods of analysis should be added to this statement. The eWG were therefore asked to consider a revised statement with the following amendments contained within square brackets to ensure that the statement contained within Section 1.2 is comprehensive and accurately reflects the content of Section A of the Standard.

- 1.2** This section of the Standard contains compositional, quality, [~~and~~] safety, [**labelling and analytical**] requirements for Follow-up Formula for Older Infants.

#### eWG views

Whilst the consensus of the eWG was to support the addition of 'labelling', 11 eWG members raised concerns over the inclusion of 'analytical' within Section 1.2. This compares to 17 eWG members who supported the inclusion of 'analytical', in addition to one CMO who would support its inclusion if this was the majority view, and a further CM who suggested that if included, 'analytical' should be defined.

#### Conclusion

Based on the views of the eWG, it is recommended that Section 1.2 of the Scope for follow-up formula for older infants be expanded to reference the labelling and analytical requirements within the Standard so that the statement is comprehensive and reflects the content of Section A. It is worth noting that the proposed text is additional to that contained within the same provision of the Infant Formula Standard.

#### Recommendation 11:

That CCNFSDU agree to the following statement for Section 1.2:

- 1.2** This section of the Standard contains compositional, quality, safety, [~~labelling and analytical~~] requirements for Follow-up Formula for Older Infants.

### 5.2.3 Scope – Section 1.3

As part of the first round of consultation, the Chairs proposed the following modified statement for follow-up formula for older infants for consideration by the eWG:

- 1.3** Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for [marketing] [**being named**] as [~~infant formula~~] [**Follow-up Formula for Older Infants**]. [~~No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.~~]

Following the first round of consultation, the majority view of the eWG to avoid the terminology ‘accepted for marketing’ was noted. A scan of various definitions for ‘marketing’ revealed that ‘marketing’ has multiple definitions and interpretations globally, with differing approaches as to whether ‘marketing’ extends to the sale, distribution, promotion and/or advertising. It was therefore considered problematic to define ‘marketing’ for the purposes of this Standard. Further to this, ‘marketing’ is not defined in the Infant Formula Standard. Recommending a definition of ‘marketing’ for inclusion in the Follow-up Formula Standard as was proposed by several eWG members in the form of a footnote, may therefore create a situation where this definition differs to what is considered to be ‘marketing’ in the Infant Formula Standard.

Various modified options for the wording of Section 1.3 of the Scope for follow-up formula for older infants, without a reference to ‘marketing’ were therefore presented to the eWG in the second round of consultation for their consideration. These were:

- OPTION 1: Only products that comply with the criteria laid down in the provisions of this section of this Standard [**should be presented as**] Follow-up Formula for Older Infants.
- OPTION 2: Only products that comply with the criteria laid down in the provisions of this section of this Standard [**may be presented as suitable for**] Follow-up Formula for Older Infants
- OPTION 3: Only products that comply with the criteria laid down in the provisions of this section of this Standard [**would be accepted for being presented as**] Follow-up Formula for Older Infants.
- OPTION 4: Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for [**being named/called**] Follow-up Formula for Older Infants.

#### eWG views

Based on comments received from the eWG, Option 1 was the preferred approach with two of the 16 eWG members who supported Option 1 suggesting that ‘*should be presented as*’ be modified to read ‘*may be presented as*’ and ‘*shall be presented as*’ respectively. One CMO suggested that the entire paragraph could be deleted altogether as the requirement contained within Section 1.3 is not present in other standards for foods for infants and young children (for example, CODEX STAN 74-1981 for *Processed Cereal-Based Foods for Infants and Young Children*). Further to this, the comment was made that the requirement appears more important in the Infant Formula Standard where it is accompanied by the additional requirement that ‘*No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life*’.

#### Conclusion

Based on the views of the eWG, with respect to Section 1.3 and noting that there is majority support for a Standard which clearly differentiates the different formula products from one another so as to avoid confusion and misuse of the respective products, it is recommended that Section 1.3 be retained for follow-up formula for older infants with the suggested text within Option 1 being the preferred approach. Consideration should however be given to the correct terminology. Whilst Option 1 uses ‘*should*’, ‘*shall*’ would be more consistent with the terminology used in the labelling section of the Standard.

#### Recommendation 12:

That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

- 1.3** Only products that comply with the criteria laid down in the provisions of this section of this Standard [**should / shall**] be presented as] Follow-up Formula for Older Infants.

### 5.2.4 Scope – Section 1.4

At CCNFSDU36 and CCNFSDU38 it was discussed that the Scope and Labelling sections could include referencing relevant WHO documents and WHA resolutions on optimal infant and young child nutrition, and on the non-necessity of these products. Previous eWGs and the Committee have continued to recognise the relevance of WHA 39.28 and have agreed that follow-up formula is not considered nutritionally necessary in the diets of older infants and young children ([REP15/NFSDU](#), para 91).

Within the 2016 eWG there were differences in opinion as to which WHA resolutions and WHO policies should be referenced, or whether they should be referenced at all.

In the 1<sup>st</sup> Consultation Paper for 2017 on the Scope and Labelling aspects, the Chairs presented information on follow-up formula for older infants in the context of WHA resolutions and WHO documents. The 2017 eWG was asked to consider if and which WHA resolutions and WHO policies are relevant to the *Standard for Follow-up Formula*, and whether these should be referenced in the Standard or whether specific provisions within the Standard, such as the labelling aspects can be drafted to reflect the intent of these resolutions and documents.

As a starting point for discussion, the Chairs provided the below text which was modified from Section 1.4 of the current Infant Formula Standard:

**1.4** The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, [**the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children**] and [relevant] World Health Assembly resolution[s] [**including WHA .....**] [WHA54.2 (2001).]

#### eWG views

Of the 38 respondents to the 1<sup>st</sup> Consultation Paper, 23 eWG members (including 1 CMO) indicated their preference for referencing one or more WHA resolutions or WHO documents within the Standard for follow-up formula for older infants. Contrary to this view, 15 eWG members either indicated a preference for no reference at all (8 eWG members), a generic statement regarding the applicability of 'relevant' documents or resolutions without citing what these might be (1 eWG member), or did not respond to the question, or articulate a clear position (6 eWG members).

The WHO document viewed by eWG members as being most relevant to follow-up formula for older infants was the 1981 [International Code of Marketing of Breast-milk Substitutes](#) (the WHO Code) with 21 eWG members (including 1 CMO) supporting a reference within the Standard for follow-up formula for older infants. It is interesting to note, that whilst two CM's supported a reference to the WHO Code, the same two members considered follow-up formula for older infants not to be a breast-milk substitute.

Second to the WHO Code, 19 eWG members supported a specific reference to either the [WHO Guidance on 'Ending inappropriate promotion of foods for infants and young children'](#) and/or its Resolution ([WHA69.9](#)) in the Standard for follow-up formula for older infants. Within the 2016 eWG, some members suggested the Follow-up Formula Standard specifically reference WHA 69.9, others preferred that consideration is given to the Resolution and associated Technical Guidance document by incorporating certain recommendations within the Labelling section of the Standard.

In addition to the above documents, 18 eWG members (including 1 CMO) cited the [WHO Global Strategy for Infants and Young Children](#) as being relevant and requiring referencing within the Standard for follow-up formula for older infants. Only 12 of these members also cited the relevant resolution WHA 54.2. Four additional CM's cited WHA 54.2 only.

There were various reasons presented by those members who are of the view that WHA resolutions and WHO documents should not be referenced in the Standard which included:

- The purpose of WHO documents and WHA resolutions is to help determine public health policies. These documents should provide direction and guidance for governments in developing their own national public health policies in accordance with their national context.
- The review of the Standard can take in to consideration the policies of WHO without the need to specifically reference individual documents or resolutions.
- Future amendments to WHO/WHA documents should not be automatically adopted as part of this Standard without first being considered by the Committee as to the relevance of these amendments. A process for reviewing any referenced document is essential if WHO/WHA documents are to be cited within the Standard.

- Not all sections of the noted WHA resolutions and WHO documents are applicable to the Standard and to follow-up formula for older infants, or to individual national contexts, leading to confusion if they were to be included.

Electronic working group member views on whether follow-up formula for older infants is considered a breast-milk substitute should be taken into account, as this will also inform consideration of applicable WHA resolutions and WHO documents.

### Conclusion

Within the 2017 eWG there were more respondents supporting reference to one or more WHO/WHA documents within the Follow-up Formula Standard than there were respondents against any form of reference, however strong positions were presented for and against referencing WHO/WHA documents. Determination of which documents may be appropriate and applicable has proved challenging.

The Codex Secretariat and WHO has worked to progress this issue and find a workable solution. There is general agreement from WHO and the Secretariat to the concept of a Preamble that includes reference to relevant documents, noting that this approach to the Preamble would replace the need to list or reference specific resolutions within different sections of the Standard itself as the Preamble is applied to the Standard as a whole. This approach would make provision 1.4 of the Scope redundant.

#### Recommendation 13:

That CCNFSDU agree to:

- include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper.
- delete provision 1.4 for follow-up formula for older infants from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.

### 5.3 Labelling – Introductory Paragraph

The Labelling section (Section 9) of the current *Standard for Follow-up Formula* sets out labelling requirements for follow-up formula products. In the introduction to Section 9 both the Codex Infant Formula and Follow-up Formula Standards refer to other general Codex labelling standards and guidelines which are applicable to these respective products.

Both the Codex Infant and Follow-up Formula Standards specifically state that the requirements of the *General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)) apply. The *Standard for Infant Formula* also specifies that the requirements of the *Guidelines on Nutrition Labelling* ([CAC/GL 2-1985](#)) and the *Guidelines for Use of Nutrition and Health Claims* ([CAC/GL 23-1997](#)) apply to infant formula and formula for special medical purposes for infants. The *Guidelines for Use of Nutrition and Health Claims* do not permit nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation (CAC/GL 23-1997).

Members of the 2017 eWG were asked if they supported the inclusion of an introductory paragraph to the Labelling section for follow-up formula for older infants, similar to that presented in Section 9 – Labelling, of the Infant Formula Standard which states that the requirements within the following Codex texts are applicable:

*General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)*

*Guidelines on Nutrition Labelling (CAC/GL 2-1985)*

*Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)*

#### eWG views

There was full support from those eWG members who responded to this question for inclusion of an introductory paragraph to the labelling section for follow-up formula for older infants with all respondents deeming a reference to applicability of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) to be appropriate. Comment was however made that the NRV's included in the *Guidelines on Nutrition Labelling* are for the general population and are therefore not appropriate for older infants, and as such, these may need to be adapted for the target audience.

The 1<sup>st</sup> Consultation Paper did not explicitly ask if the *Guidelines for Use of Nutrition and Health Claims* should be referenced in an introductory paragraph to the Labelling section for follow-up formula for older infants as nutrition and health claims were explored separately, see discussion below.



### 5.3.1 Ingredient and nutrient declarations/claims

The 2017 eWG was tasked by the Committee to examine the promotional aspect of follow-up formula for older infants and [name of product] for young children, as well as misleading claims (REP17/NFSDU para.118). The 1<sup>st</sup> Consultation Paper therefore did not explicitly ask if the *Guidelines for Use of Nutrition and Health Claims* should be referenced in an introductory paragraph to the Labelling section for follow-up formula for older infants as nutrition and health claims were explored separately.

The purpose of declaring nutrition information is to provide caregivers with adequate information to be able to make informed decisions about the appropriate use of these products. The *Declaration of Nutritive Value* and the *List of Ingredients* are the primary elements on follow-up formula that are currently permitted as means of providing nutrition information to caregivers.

Previous eWG's have not explored whether claims should be *specifically provided for* in the Follow-up Formula Standard, nor whether permissions for the provision of information, including declarations about nutrients, ingredients, the nutrition content, and any health effects should extend beyond what is currently permitted for follow-up formula as part of the ingredient list or declaration of nutritive value.

#### **Guidelines for Use of Nutrition and Health Claims**

Section 1.4 of the Scope of the *Guidelines for Use of Nutrition and Health Claims* states that;

*'Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation'*,

The following information is also relevant:

The *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) state that:

*Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.*

*Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.*

Section 3.4 of the *General Guidelines on Claims* includes the following prohibition for claims:

*Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are:*

*(a) in accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines.*

*or,*

*(b) in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.*

#### **eWG views**

As part of the first round of consultation, eWG members were asked whether voluntary declarations about nutrients and ingredients should be permitted on follow-up formula for older infants. Members in support of voluntary declarations were asked what type(s) of declaration/claim should be permitted and how should they be regulated. They were encouraged to consider both the declaration of mandatory compositional parameters and of optional nutrient and ingredient provisions.

Twenty one eWG members did not support voluntary nutrient or ingredient declarations being permitted for follow-up formula for older infants, noting that two of these respondents were of the view that an exception should be made for indications relating to the lactose content (such as 'contains lactose', 'lactose free'), and one member thought this should also be the case for declarations about DHA (e.g. 'contains DHA'). In order for such declarations to be made, parameters for what would constitute 'lactose free', 'low lactose' would need to be established. Comment was made by many respondents that product for older infants is a breast-milk substitute and as such provisions for follow-up formula for older infants should align with the approach taken in the Infant Formula Standard (which does not include any explicit permissions for voluntary declarations), and that they should not contradict the WHO Code. Two eWG members expressed the view that voluntary declarations about nutrients and ingredients can be perceived to be advertising or promotion of product and have the potential to confuse and undermine breastfeeding.

Contrary to the view that declarations should not be permitted, 11 eWG members supported declarations of some sort. Within this group, comment was made that nutrition claims that support national nutrition policies should be permitted. It would appear that the current wording of section 1.4 of the Scope for the *Guidelines for Use of Nutrition and Health Claims* which states that;

*'Nutrition and health claims shall not be permitted for foods for infants and young children **except where specifically provided for in relevant Codex standards or national legislation**'* (emphasis added) would allow for national authorities to include provisions for claims (that align with national nutritional policies) on follow-up formula for older infants in their own national legislation.

Whilst there were some members who supported declarations for both mandatory and optional nutrients and ingredients, others were of the view that voluntary declarations for optional ingredients only should be permitted. Whilst not all of those respondents that supported voluntary declarations, commented on what type(s) of claims should be permitted, only two members explicitly supported health claims. Others appeared to favour content claims provided optional ingredients are within minimum and maximum levels stipulated in the Standard, or the claims relate to the presence or absence of an ingredient or nutrient (in association with regulated minimum and maximum levels or are above a stipulated percentage of the daily reference intake for that nutrient). Several members noted Nutrient Reference Values should therefore be established for this age group.

## Conclusion

Claims and declarations on the label of follow-up formula for older infants continues to be a very contentious issue, with no clear direction on what approach should be taken. From those members who support some form of claim or declaration on follow-up formula for older infants, it would appear from the comments received that there is more interest in content claims and the ability for labels to communicate the composition (or change in composition) of the product to consumers, rather than for health claims.

Due to the lack of consensus and the complexity of issues associated with establishing parameters for different types of claims and declarations for follow-up formula for older infants, and in accordance with the views of the eWG, it is recommended that the same approach as that taken in the Infant Formula Standard should also be applied to follow-up formula for older infants. That approach would see the inclusion of a reference to the applicability of the recommendations in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) to follow-up formula for older infants. It would also include a statement that the prohibition on the use of nutrition and health claims contained within the Guidelines exists except where *'specifically provided for in relevant Codex Standards or national legislation'*.

This approach whilst still allowing for declarations and claims if included in future revisions of relevant Codex Standards, or in national legislation, would be the most pragmatic approach to what continues to be an issue of contention and divergent views, and is consistent with the current Codex approach.

In addition, and in accordance with the unanimous support of the eWG, it is proposed that the introductory paragraph to the labelling section for follow-up formula for older infants also include reference to the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).

### Recommendation 14:

That CCNFSDU agree to the following introductory paragraph to the Labelling Section for follow-up formula for older infants (Section A):

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)), the *Guidelines on Nutrition Labelling* ([CAC/GL 2-1985](#)) and the *Guidelines for Use of Nutrition and Health Claims* ([CAC/GL 23-1997](#)) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

### 5.3.2 Nutrient Reference Values (NRVs) for infants and young children

The 2017 eWG was also asked to consider whether nutrition claims should be revisited after the completion of NRVs for the older infant and young child age group (6 – 36 months). **Nutrition claim** means any representation which states, suggests or implies that a food has particular nutritional properties including, but not limited to, the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

#### eWG views

The 2017 eWG was split in its views on whether nutrition claims for follow-up formula for older infants should be revisited after the completion of NRVs for the older infant and young child age group (6 – 36 months). Comments received and concerns raised included the following:

- As follow-up formulas for older infants are breastmilk substitutes, application of the same requirements within the Codex Infant Formula Standard is appropriate and hence revisiting nutrition claims after the development and completion of NRVs for older infants and young children would not be required.
- Any nutrition and health claims should be prohibited for follow-up formula for older infants consistent with the WHO International Code of Marketing of Breastmilk Substitutes.
- If progressed, the development and completion of NRVs for older infants and young children would most likely be a lengthy process which would possibly require the reopening of the Follow-up Formula Standard. As such, it was suggested by some eWG members that the Committee may wish to consider an approach that does not require the reopening of the Standard. It was suggested that the Committee could consider the appropriateness of nutrient content claims once the nutrient composition of follow-up formula for older infants is finalised with the Standard allowing for nutrition claims that can be substantiated by a credible scientific body such as JEMNU, and after a complete scientific review. Alternatively, it was suggested that the Introductory Paragraph to the Labelling Section could reference the *Guidelines for Use of Nutrition and Health Claims* ([CAC/GL 23-1997](#)), and this could be further modified to state that: ‘*Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition and health claims may be permitted for the foods that are the subject of this Standard provided that they have been demonstrated in rigorous studies with adequate scientific standards. The use of nutrition claims based on Nutrient Reference Values (NRVs) is permitted as soon as NRVs specifically for older infants are adopted by Codex.*’

#### Recommendation 15:

A decision on the need to revisit nutrition claims on the completion of NRVs for infants and young children is not required by CCNFSDU at this point in time.

It is recommended that CCNFSDU agree that the progress of reviewing this Standard should not be delayed and that any consideration of NRVs (if established for this age group) and the purpose of such NRVs in the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985), including the need to consider whether any labelling provisions within Codex standards for foods for infants and young children need to be revisited if NRVs are adopted by Codex, should form part of the ToR for a NRV working group.

Noting that the Committee cannot foresee the outcome of any work on NRVs for this age group should it proceed, it is recommended that the status quo for nutrition (and health) claims, that is; that the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation, remain.

## 5.4 Labelling - Name of the Product

Based on comments received from eWG members to the 1<sup>st</sup> Consultation Paper, the below drafting of Section 9.1 was recommended for follow-up formula for older infants. The main concern expressed during the first round of consultation relating to Section 9.1 – The Name of the Product, was the wording of provision 9.1.4. It was suggested that the wording of 9.1.4 should be modified to include milk from animals/sources other than cows. Consideration should therefore be given to including provisions for labelling when soy or other protein sources (such as goats’ milk) are used, noting that this could also be covered by provision 9.1.3.

Some suggested that 9.1.4 could be deleted as this section becomes redundant if the sources of protein(s) are indicated as per provision 9.1.3. Others were however supportive of retaining provision 9.1.4 and labelling which specifically indicates when cows' milk (or other protein sources such as goat or soy) are the only source of protein present in the product.

It was proposed that the wording of 9.1.4 be modified to state; *If cows' milk is the only source of protein, the product may be labelled "Follow-up Formula for Older Infants Based on Cows' Milk [Protein]"*. It was thought that *'based on cows' milk protein'* was a more factual reflection of the composition as most of the components in a formula based on cows' milk protein are often not derived from cows' milk, therefore *'based on cows' milk'* is not correct and adequate.

It was suggested that in order to be able to use the qualifier *'based on cows' milk'*, the provision should require more than only the origin of the protein. Consideration should therefore be given to inclusion of a provision similar to Section 3.3.1.2 of the current Follow-up Formula Standard as qualification for when Follow-up Formula for Older Infants may be labelled *'based on cows' milk'*.

Section 3.3.1.2 states that follow-up formula based on milk must represent a minimum of 90% of the total protein derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk.

In addition to the above comments, one CMO asked that 9.1.2 be modified to include a reference to *'regional'* usage after *'national'* in order to take into account the situation of the EU. Concerns were also expressed over the use of the term *'milk'* in the title as this may suggest that *'milk'* is the predominant ingredient which may not always be the case, particularly in products with reduced protein levels.

The below drafting was presented to the eWG for their consideration at the second round of consultation:

Name of the Product	
<b>9.1</b>	<b>The Name of the Product</b>
<b>9.1.1</b>	The text of the label and all other information accompanying the product shall be written in the appropriate language(s).
<b>9.1.2</b>	The name of the product shall be <i>Follow-up Formula for Older Infants</i> as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [ <b>or regional</b> ] usage.
<b>9.1.3</b>	The sources of protein in the product shall be clearly shown on the label.
<b>9.1.4</b>	If <del>cows'</del> [ <b>name of animal/plant-based</b> ] milk is the only source of protein, the product may be labelled 'Follow-up Formula for Older Infants Based on <del>cows'</del> [ <b>name of animal/plant based</b> ] milk [ <b>protein</b> ]'.
	<b>OR</b>
	[If 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content, the product may be labelled 'Follow-up Formula for Older Infants based on [name of animal] Milk].
	<b>OR</b>
	[Delete 9.1.4, covered by 9.1.3]
<b>9.1.5</b>	A product which contains neither milk nor any milk derivative [ <b>shall</b> ] [ <b>may</b> ] be labelled "contains no milk or milk products" or an equivalent phrase.

**eWG views**

In relation to the above proposed drafting, the 2017 eWG had the following views:

**5.4.1 Name of Product – Provision 9.1.2**

There was majority support for adopting the proposed text for provision 9.1.2 with the inclusion of *'regional'* to take account of the situation within the EU.

**Name of Product – Provision 9.1.4**

Within provision 9.1.4, the eWG was split between its support for the first option presented (or a modification of this) and the third option which would see the deletion of provision 9.1.4 as it is covered by provision 9.1.3. It was suggested that the first option could be split into two separate provisions so that milk-based and plant-based products are presented separately. Concern was expressed over the use of the term 'milk' in association with 'plant-based' products as 'plant-based milk' is not actually 'milk'.

Further to this, several eWG members commented that individual amino acids may need to be added to follow-up formula for older infants to reach adequate protein quality. As such, it was the view of these eWG members that some guidance may be required, for example within a footnote, to clarify that the labelling provision based on 'only source of protein' as presented and proposed within 9.1.4 would not preclude the addition of these amino acids.

#### 5.4.2 Name of Product – Provision 9.1.5

Within the second round of consultation, it was noted that within provision 9.1.5, the Infant Formula Standard uses the term 'shall' whereas the current Follow-up Formula Standard uses the term 'may' within the same provision. Members of the eWG were asked to select their preferred approach. There was majority support for deleting 'may' and removing the square brackets from 'shall'.

#### Conclusion

As there was majority support within the eWG for the wording proposed for 9.1, 9.1.1, 9.1.2, 9.1.3, it is recommended these provisions be adopted as presented below. Based on the views of the eWG, the following recommendation is made in relation to the remaining provisions within Section 9.1.

#### Recommendation 16:

That CCNFSDU agree to the following text for Section 9.1 – The Name of the Product, and select its preferred option for provision 9.1.4, including the text within square brackets.

#### 9.1 The Name of the Product

**9.1.1** The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

**9.1.2** The name of the product shall be *Follow-up Formula for Older Infants* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national {or regional} usage.

**9.1.3** The sources of protein in the product shall be clearly shown on the label.

**9.1.4** OPTION 1: Split provision 9.1.4 into two:

**9.1.4(a)** If [name of animal] milk is the only source of protein[\*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

**9.1.4(b)** If [name of plant] is the only source of protein[\*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].

[\* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

**OR**

OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

**9.1.5** A product which contains neither milk nor any milk derivative [~~shall~~] [~~may~~] be labelled "contains no milk or milk products" or an equivalent phrase.

#### 5.5 Labelling - List of Ingredients

In the 1st Consultation Paper, it was proposed that provisions 9.2.1 and 9.2.2 (relating to the List of Ingredients) of the Infant Formula Standard be adopted for follow-up formula for older infants.

There was almost full support from the eWG for this approach. It was requested that some flexibility be given to provision 9.2 to accommodate national or regional regulations. Further to this, it was suggested that the functional use, and optionally the declaration of the INS number, for additives should be permitted.

Further comment was received that suggested that provision 9.2.1 should include declaration of optional ingredients, to ensure relevant compositional information is provided for use by both health care professionals and consumers.

As a result of eWG feedback to the 1<sup>st</sup> Consultation Paper, the following modified drafting for Section 9.2 – List of Ingredients was presented to the eWG for their consideration.

<b>List of Ingredients</b>	
<b>9.2</b>	<b>List of Ingredients</b>
<b>9.2.1</b>	A complete list of ingredients [ <b>including optional ingredients</b> ] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.
<b>9.2.2</b>	The specific name shall be declared for ingredients of animal or plant origin and for food additives. [ <b>Food additives may also optionally declare the INS number</b> ].

#### **eWG views**

With respect to provision 9.2.1, it was the majority view of the eWG that the text [**including optional ingredients**] be deleted. It was the view of many that this proposed text was redundant as it is captured by the requirement within the provision for a '*complete list of ingredients*' which extends to optional ingredients.

In relation to provision 9.2.2 there was majority support for adopting the draft text as proposed, including the statement; 'Food additives may also optionally declare the INS number'.

#### **Conclusion**

Based on the views of eWG, it would appear that the majority of respondents do not see a need for provision 9.2.1 to specifically state that optional ingredients also need to be included in the ingredients list. Further to this, it would appear that the majority of respondents are not opposed to including a statement that in addition to the specific name, food additives may also declare the INS number.

<b>Recommendation 17:</b>	
That CCNFSDU agree to the following text for Section 9.2 – List of Ingredients.	
<b>9.2</b>	<b>List of Ingredients</b>
<b>9.2.1</b>	A complete list of ingredients [ <del>including optional ingredients</del> ] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.
<b>9.2.2</b>	The specific name shall be declared for ingredients of animal or plant origin and for food additives. [ <del>Food additives may also optionally declare the INS number</del> ].

#### **5.6 Labelling – Declaration of Nutritive Value**

In the 1<sup>st</sup> Consultation Paper, the Declaration of Nutritive Value clause of the Infant Formula Standard was modified to reference follow-up formula for older infants rather than infant formula, and the text 'grammes' was replaced with 'grams'. This modified text was presented to eWG members for their comment.

Whilst there was majority support for the drafting text as presented in the 1<sup>st</sup> Consultation Paper, several minor modifications were suggested. Several members highlighted discrepancies in the numbering of the Proposed Draft Revised Standard for Follow-up Formula presented at Appendix IV in REP/17 NFSDU. It would appear the numbering in Appendix IV is incorrect and should be presented as:

3. ESSENTIAL COMPOSITON AND QUALITY FACTORS
  - 3.1 Essential Composition
  - 3.2 Optional Ingredients (not 3.3.2)

It was also requested that some flexibility be given to Section 9.3 to accommodate national or regional regulations.

Comment was made that the declaration of nutrition information should start with per 100ml of the food ready for use. This was supported by others who considered the declaration of nutrition information per 100ml in ready for use product, or as prepared according to the instructions on the label to be of more value to consumers than per 100 grams. It was also suggested that Section 9.3 should include a paragraph that permits the information per serving on an optional basis.

Based on the comments received from eWG members to the 1<sup>st</sup> Consultation Paper, and majority support for adopting the modified Declarations of Nutritive Value adapted from the Infant Formula Standard, the below drafting for Section 9.3 was presented at the second round of consultation with some minor additions included in square brackets for consideration by the eWG.

<b>Declaration of Nutritive Value</b>
<p><b>9.3 Declaration of Nutritive Value</b></p> <p>The declaration of nutrition information [<b>for follow-up formula for older infants</b>] shall contain the following information which should be in the following order:</p> <ol style="list-style-type: none"> <li>a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [<b>as well as</b>] [<b>or</b>] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</li> <li>b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold [<b>as well as</b>] [<b>or</b>] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</li> <li>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</li> </ol>

#### **eWG views**

Many respondents commented that they consider the declaration of nutrition information per 100ml of the food ready for use to be of most value to consumers. This view was supported by one CMO who also noted, that whilst this might be the case, the declaration of nutrition information per 100g as sold would also be relevant for health professionals. Concern was expressed over allowing manufacturers the choice between the option of declaring nutrition information either per 100 grams or per 100 millilitres of the food as sold **or** per 100 millilitres of the food ready for use, when prepared according to the instructions on the label, as this could create confusion when comparing products.

#### **Conclusion**

The preference of the eWG is to require the declaration of nutrition information per 100 grams or per 100 millilitres of the food as sold in addition to per 100 millilitres of the food ready for use, when prepared according to the instructions on the label. It is therefore concluded that the drafting text should include the text 'as well as' and delete 'or' as presented below.

<p><b>Recommendation 18:</b></p> <p>That CCNFSDU agree to the following drafting text for Section 9.3 – Declaration of Nutritive Value.</p> <p><b>9.3 Declaration of Nutritive Value</b></p> <p>The declaration of nutrition information {for follow-up formula for older infants} shall contain the following information which should be in the following order:</p> <ol style="list-style-type: none"> <li>a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold {as well as} {or} per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</li> <li>b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold {as well as} {or} per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</li> <li>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</li> </ol>
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## 5.7 Labelling – Date Marking and Storage Instructions

The *General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)), is currently under review. This includes the date labelling conventions being finalised by the Codex Committee on Food Labelling (CCFL). Based on the comments received from the eWG and noting the need to be consistent with the outcome of any decisions made at CCFL, the below modified text which aligns with the wording of the date marking sections put forward at CCFL43 be adopted for follow-up formula for older infants. It is understood that within the *Proposed Draft Revisions to the General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) (*At Step 5 as of September 2017*) only the exemption section remains in square brackets. It is however important to note that as the full standard has not yet been completed it is possible that other areas could still change.

Date Marking and Storage Instructions	
<b>9.4</b>	<b>Date Marking and Storage Instructions</b>
<b>9.4.1</b>	<p>The <b>“Best Before Date” or “Best Quality Before Date”</b> <del>date of minimum durability (preceded by the words “best before”)</del> shall be declared by the day, month and year <del>in uncoded numerical sequence</del> except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] will suffice. <del>The month may be indicated by letters in those countries where such use will not confuse the consumer.</del> [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]</p> <p>In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.</p>
<b>9.4.2</b>	<p>In addition to the date, any special conditions for the storage of the food shall be indicated <del>if</del> [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.</p> <p>Where practicable, storage instructions shall be in close proximity to the date marking.</p>
<b>Recommendation 19:</b>	
<p>As this paper was written prior to CCFL44, it is recommended that CCNFSDU agree to modify the above text (as necessary) and adopt any changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017.</p>	

## 5.8 Labelling – Information for Use

During the first round of consultation, the eWG was asked to consider if the Follow-up Formula Standard requires the level of prescription contained within section 9.5 of the Infant Formula Standard, and whether different approaches might be required for the different products; infant formula, follow-up formula for older infants, and [name of product] for young children.

It is worth noting that *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) which covers the ‘*production, preparation and use of products available in powdered form, referred to as Powdered Formulae (PF)*’ currently forms part of Section 6 – Hygiene of both the current Follow-up Formula Standard and the Infant Formula Standard. Despite the views of some eWG members, it is proposed that the revised Follow-up Formula Standard align with the approach taken in the Infant Formula Standard and any reference to this Code be included within Section 6 – Hygiene, of the revised Follow-up Formula Standard rather than replicating it within Section 9.5.

The current provisions in the Infant Formula Standard are as follows:

<b>9.5</b>	<b>Information for Use</b>
<b>9.5.1</b>	<p>Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.</p>



<b>9.5.2</b>	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.
<b>9.5.3</b>	The label shall carry clear graphic instructions illustrating the method of preparation of the product.
<b>9.5.4</b>	The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.
<b>9.5.5</b>	Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.

By comparison, the current Follow-up Formula Standard contains a single provision that relates to the safe preparation, storage and use of product, in addition to two other 'information for use' provisions relating to the appropriate age of introduction of follow-up formula, and the need for infants and children fed follow-up formula to receive other complementary foods in addition to the formula.

In the 1<sup>st</sup> Consultation Paper, the following were proposed in relation to Section 9.5 for follow-up formula for older infants;

- Re-word the title of Section 9.5 of the Follow-up Formula Standard to; Information for [Use] ~~Utilization~~, to align with the Infant Formula Standard.
- Retain a requirement for the labelling of follow-up formula for older infants to have a statement that follow-up formula for older infants shall not be introduced before the 6<sup>th</sup> month of life.
- Retain a requirement for the labelling of follow-up formula for older infants to have information that older infants shall receive other foods in addition to the formula.

Electronic working group members were asked to comment on whether any of the provisions contained within section 9.5 of the Infant Formula Standard should be adopted for follow-up formula for older infants, and whether any additional 'information for use' provisions should be considered by the eWG for inclusion in the Standard for follow-up formula for older infants.

#### **eWG views expressed in the first round of consultation**

There was majority support for the proposal that a requirement for the labelling of follow-up formula for older infants include a statement that follow-up formula shall not be introduced before the 6<sup>th</sup> month of life. Several comments were received on how the age range should be referenced within this statement, with concern expressed over the use of the term '*before the 6<sup>th</sup> month*'.

Three respondents felt that labelling requirements for follow-up formula for older infant should align with WHA69.9, specifically Recommendation 4 of the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children. The following statement was recommended by all three supporters; '*Exclusive breastfeeding is recommended from birth to 6 months of age, and at 6 months appropriate complementary foods should be introduced while continuing to breastfed until 2 years of age or beyond*'. This statement is consistent with WHO recommendations ([Guiding principles for complementary feeding of the breastfed child](#), Pan American Health Organization, 2003).

Requirements for the role of breastfeeding in the diet of infants and labelling provisions that do not discourage breastfeeding are also considered under Section 9.6 – Additional Labelling Provisions.

Comment was received that noted in EU legislation (Article 6(3)(a) of delegated Regulation (EU) 2016/127), a statement on the appropriate use of the product is required as follows; '*a statement that the product is suitable only for infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs*'. In addition, EU legislation (Article 6(3) (b) of delegated Regulation (EU) 2016/127) requires the label of follow-on formula to bear '*instructions for appropriate preparation, storage and disposal of the products and a warning against the health hazards of inappropriate preparation and storage*'.

There was full support from eWG respondents for retaining the requirement for the label of follow-up formula for older infants to include information that older infants shall receive other foods in addition to the formula. Members felt strongly that the label of follow-up formula for older infants should clearly communicate the role of the product in addition to complementary foods as part of a diversified diet. This requirement will assist in avoiding confusion that follow-up formula alone cannot fulfil all the nutrient needs of the older infant, as well as distinguishing it from other formula products.

Several members noted that this requirement may be redundant under Section 9.5 – Information for Use, as a similar provision is contained within Section 9.6 – Additional Labelling Requirements (**9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months**). The 1<sup>st</sup> Consultation Paper noted this and recommended provision 9.6.4 be removed from Section 9.6 and be covered under Section 9.5 instead.

Of those eWG members who responded to the request for comment on whether any of the provisions contained within Section 9.5 of the Infant Formula Standard should be adopted for follow-up formula for older infants, there was majority support for adoption of all of the provisions. These eWG members deemed the Section 9.5 provisions to be applicable to follow-up formula for older infants as they contain important information for the appropriate handling, preparation, storage and use of product. Comment was also received that visual descriptions of the method of preparation are of added value.

Electronic working group members were asked to comment on whether there are any additional 'information for use' provisions that should be considered for inclusion in the Standard for follow-up formula for older infants. Most respondents considered that there is no need for additional provisions for follow-up formula for older infants, in addition to those discussed above. Some comments were received including the request that the label communicate that breast-milk is best for babies up to two years of age and beyond, the request for the *Code of Hygiene Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)* to be cited, and the suggestion that a statement relating to the non-sterile nature of the product be included on the label. It is worth noting that this is not a requirement for infant formula, and as such should not be necessary for follow-up formula for older infants.

In line with the content of Section 9.5 – Information for Use of the current Follow-up Formula Standard, it was proposed that the provisions contained within Section 9.5 relate to how the product should be used, including the safe preparation, use and storage of product, the requirement not to 'use' follow-up formula for older infants before the age of 6 months, and the requirement for follow-up formula for older infants to be 'used' in addition to appropriate complementary foods. Comments received from some eWG members relating to the role of breastfeeding in the diet of infants, and labelling provisions that do not discourage breastfeeding were noted. It is proposed that these are considered under Section 9.6 – Additional Labelling Provisions.

Based on the comments received from eWG members to the 1<sup>st</sup> Consultation Paper, two approaches for Section 9.5 were presented for eWG consideration at the second round of consultation. As an alternative to itemising the 'information for use' labelling requirements (as per the Infant Formula Standard) and presenting these as individual provisions (Option 1), an alternative option was presented (Option 2) where the requirements were merged into two paragraphs. It was thought this second approach may assist in avoiding any repetition and duplication. It was also considered that 'Information for Use' provisions or statements should not be more stringent for follow-up formula for older infants, than what is currently required for infant formula.

The two options are replicated below:

Information for Use	
<b>Option 1:</b>	
<b>9.5</b>	<b>Information for Use</b>
<b>9.5.1</b>	Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
<b>9.5.2</b>	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula [ <b>product</b> ] remaining after feeding should be discarded, shall appear on the label [ <del>and in any accompanying leaflet</del> ].
<b>9.5.3</b>	The label shall carry clear graphic instructions illustrating the method of preparation of the product.

<p><b>9.5.4</b> The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.</p> <p><b>9.5.5</b> Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [<del>and in any accompanying leaflet</del>].</p> <p><b>[9.5.6 The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, [is not to be used as a sole source of nutrition] and that older infants should receive complementary foods in addition to the formula.]</b></p>
<p><b>Option 2:</b></p> <p><b>9.5 Information for Use</b></p> <p><b>[The following 'Information for use' requirements are mandatory provisions that must appear on the label of follow-up formula for older infants;</b></p> <p><b>9.5.1 a statement that powdered follow-up formula for older infants should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation, adequate directions for the appropriate preparation, handling and use of product, including its storage and disposal after preparation in accordance with Good Hygienic Practice. The label shall also carry clear graphic instructions illustrating the method of preparation of the product, a warning about the health hazards of inappropriate preparation, storage and use, and adequate directions regarding the storage of the product after the container has been opened.</b></p> <p><b>9.5.2 a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition, and that older infants should receive complementary foods in addition to the formula.]</b></p>

#### eWG views expressed in the second round of consultation

There was almost unanimous support for Option 1 with only two members supporting Option 2. One CMO indicated they could support either option but noted that Option 1 would mostly likely ensure more clarity.

#### 5.8.1 Information for Use – Provision 9.5.1

Whilst no comments were sought on provision 9.5.1 of Option 1, one CM suggested alternative wording to make this provision more succinct. The suggested modification is as follows:

9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [~~Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.~~] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

Other suggestions were made which would require more detail on the label of follow-up formula for older infants than that which is required for infant formula – such as specifying the water temperature. These suggestions have not be included in the proposed drafting text.

#### 5.8.2 Information for Use – Provision 9.5.2

There was majority support within the eWG for replacing '*formula*' with '*product*' and for deleting the previously proposed text in square brackets.

#### 5.8.3 Information for Use – Provision 9.5.3 and 9.5.4

No comment was sought on provision 9.5.3 and 9.5.4. Comment was received from one CM who suggested that pictures of feeding bottles should not be permitted on labels of follow-up formula for older infants. It was noted that there is a redundant '*and*' within provision 9.5.4.

#### 5.8.4 Information for Use – Provision 9.5.5

Of those members who commented on the deletion of the text '*and in any accompanying leaflet*' within provision 9.5.5, there was majority support for this approach. Only five eWG members supported retaining the text within the square brackets.

### 5.8.5 Information for Use – Provision 9.5.6

Seventeen eWG members supported the inclusion of all text contained within the square brackets. Comments received on this draft provision included; ‘*formula*’ should be replaced with ‘*product*’ to be consistent with 9.5.2, and the statement ‘*is not to be used as a sole source of nutrition*’ should be deleted as it is redundant due to the requirement for the label to already state that older infants should receive complementary foods in addition to the product.

One CMO was of the view that in line with EU legislation (Article 6(3)(a) of delegated Regulation (EU) 2016/127) which includes the requirement that the label should include information that ‘***the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant’s specific growth and development needs***’ a similar provision should be included within Section 9.5. It was deemed important that a statement similar to that above would highlight the importance of health professional input and advice for deciding when to begin complementary feeding, including any exception to six months of age, taking into account individual growth and development needs. It was identified that such an approach would ensure consistency with provision 10.2.4.1 of the *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8 – 1991) which states that ‘*the label shall include a statement indicating that the decision when precisely to introduce formulated complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the individual infant’s specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold*’. The *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 074-1981, REV. 1-2006) includes provision 8.6.4 requiring a slightly modified version of the above statement which refers to ‘*when to precisely begin complementary feeding*’ rather than *when ‘precisely to introduce formulated complementary feeding’*.

### Conclusion

There was majority support for the provisions contained within Section 9.5 and adoption of the proposed modifications within the separate provisions. It is worth noting that under provision 9.6.1 (c), it is proposed that a requirement for a statement that the product should only be used on advice of an independent health worker be included on the label of follow-up formula for older infants. It is therefore concluded that the statement recommended by the CMO and as presented above would not be required.

#### Recommendation 20:

That CCNFSDU agree to the following text for Section 9.5 and consider the proposed rewording of provision 9.5.1:

#### 9.5 Information for Use

- 9.5.1** [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [~~Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.~~] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
- 9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that {product} remaining after feeding should be discarded, shall appear on the label.
- 9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product.
- 9.5.4** The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.
- 9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
- {9.5.6}** The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, [~~is not to be used as a sole source of nutrition~~] and that older infants should receive complementary foods in addition to the product.]

## 5.9 Labelling – Additional Labelling Requirements

The Infant Formula Standard contains additional labelling requirements which are largely based on Article 4 of the WHO Code. By comparison, the current Follow-up Formula Standard only has one additional requirement which is that the *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'*.

In the 1<sup>st</sup> Consultation Paper, the 2017 eWG were asked to consider whether this requirement under section 9.6 of the current Follow-up Formula Standard should be retained for follow-up formula for older infants.

Of the 38 respondents to the 1<sup>st</sup> Consultation Paper, 24 eWG members (including 1 CMO) were of the view that the above statement should not be retained within the Standard for follow-up formula for older infants, with 21 of these members specifically expressing the opinion that they consider follow-up formula for older infants to be a breast-milk substitute. Contrary to this view, eight eWG members supported retaining the statement. One CMO felt the statement was unnecessary and confusing given the different views on what constitutes a breast-milk substitute.

Of those in favour of deleting the statement; *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'*, several cited WHA69.9 and the associated WHO technical guidance as clarification of what should be considered to be a breast-milk substitute. Whereas several members who were in support of retaining the statement commented that the 'majority of the opinions expressed during the last session of CCNFSDU were in support of these products not being breast-milk substitutes'. Some of these members also cited the Infant Formula Standard which states that; *'no product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life'* as justification as to why follow-up formula for older infants should not be considered a breast-milk substitute.

Electronic working group members were then asked to comment on whether the individual provisions (9.6.1, 9.6.2 and 9.6.3) within Section 9.6 of the Infant Formula Standard should be adopted for follow-up formula for older infants. It was proposed that provision 9.6.4 be deleted, as whilst relevant, the requirement to include a statement on the label that older infants should receive complementary foods in addition to follow-up formula for older infants is to be covered under Section 9.5. With respect to provision 9.6.5, it was proposed that a similar provision be adopted for follow-up formula for older infants.

The current provisions in the Infant Formula Standard are as follows:

### 9.6 Additional Labelling Requirements

**9.6.1** Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- a) the words "important notice" or their equivalent;
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.

**9.6.2** The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

**9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used.

**9.6.4** Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

**9.6.5** The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

### eWG views expressed in the first round of consultation

There was general agreement amongst eWG members that the labelling of follow-up formula for older infants should not discourage breastfeeding. In response to questions on Section 9.5 – Information for Use, several members commented on the need to communicate on the label of follow-up formula for older infants the importance of continued breastfeeding. It was proposed that statements relating to breastfeeding should sit under Section 9.6 as per the approach taken in the Infant Formula Standard.

With respect to provision 9.6.2, there was majority support for adopting the text as written in the Infant Formula Standard for follow-up formula for older infants. Some amendments were suggested by the eWG including:

- Deletion of ‘infant’ from the statement
- Edit the statement so that ‘infant formula’ is replaced with ‘follow-up formula for older infants’
- Edit the statement and remove the reference to ‘women’ as it is irrelevant and inappropriate
- Merge with provisions 9.6.1 and 9.6.3.

It was the suggestion of some eWG members that provision 9.6.2 be modified to include elements of WHA69.9 and the associated WHO technical guidance.

There was majority support within the 2017 eWG for adopting provision 9.6.3 of the Infant Formula Standard for follow-up formula for older infants.

There was majority support from the eWG for adopting a provision similar to that contained within provision 9.6.5 of the Infant Formula Standard for follow-up formula for older infants to enable clear differentiation of the different formula products from one another so as to avoid confusion and misuse of the respective products.

Based on comments received to the 1<sup>st</sup> Consultation Paper, further options for how the ‘additional labelling provisions’ might be presented in the Standard were presented to the eWG. Option 1 merged provisions 9.6.1, 9.6.2 and 9.6.3. Option 2 retained individual provisions and included various options for how these could be drafted. The approach was taken whereby any additional labelling requirements for follow-up formula for older infants should not be more stringent than what is required on the label of infant formula.

Additionally, based on eWG comments, it was proposed that the statement; *‘products covered by this standard are not breast-milk substitutes and shall not be represented as such’* which is included in the current Follow-up Formula Standard, should not be retained for follow-up formula for older infants.

The two options for the additional labelling requirements that were presented to the eWG are replicated below:

<b>Additional labelling requirements</b>
<b>Option 1:</b> Merges 9.6.1, 9.6.2, 9.6.3 (to become 9.6.1), deletes 9.6.4, and presents modified wording (and renumbering to become 9.6.2) for the original provision 9.6.5:
<p><b>9.6 Additional Labelling Requirements</b></p> <p><b>[9.6.1 The label of follow-up formula for older infants shall include a statement as to the superiority of breastfeeding or breast milk. The label shall have no image, text or representation that could undermine or discourage breastfeeding or which idealises the use of follow-up formula for older infants. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label.]</b></p> <p><b>[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes.</b></p> <p><del><b>[9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.]</b></del></p>
<b>Option 2:</b> Retains individual provisions for 9.6.1, 9.6.2, 9.6.3, deletes provision 9.6.4, and presents modified wording (and renumbering to become 9.6.4) for the original provision 9.6.5:
<p><b>9.6 Additional Labelling Requirements</b></p> <p><b>9.6.1</b> Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:</p> <p>[a) the words "important notice" or their equivalent;]</p> <p>b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;</p> <p>[c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]</p>

<p><b>(d) the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.]</b></p> <p><b>OR</b></p> <p><b>[9.6.1 The label of Follow-up Formula for Older Infants should not discourage breastfeeding. It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond.]</b></p>
<p><b>AND</b></p> <p><b>9.6.2</b> The label shall have no pictures of infants <del>[and women]</del> nor any other picture or text which idealizes the use of <del>[infant]</del> [follow-up] formula [for older infants].</p> <p><b>OR</b></p> <p><b>[9.6.2</b> The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might:</p> <p><b>9.6.2.1</b> suggest use for infants under the age of 6 months (including references to milestones and stages);</p> <p><b>9.6.2.2</b> recommend or promote bottle feeding;</p> <p><b>9.6.2.3</b> undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;</p> <p><b>9.6.2.4</b> convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]</p>
<p><b>AND</b></p> <p><b>9.6.3</b> The terms "humanized", "maternalized" or other similar terms shall not be used. <b>[In addition, the product should not be compared to breast-milk].</b></p>
<p><b>AND</b></p> <p><b>[9.6.4]</b> Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes.</p> <p><del><b>[9.6.4]</b> Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.]</del></p>

### **eWG views expressed in the second round of consultation**

There was majority support for Option 2 as presented above. One CMO was of the view that Option 1 would allow for some level of flexibility at the national level, but stated that they could support both options presented. The view that labelling requirements for follow-up formula for older infants should not be more stringent than what is required on the label of infant formula was expressed by several members.

#### **5.9.1 Additional Labelling Requirements – Provision 9.6.1**

There was majority support for the wording of the first option presented for provision 9.6.1. In addition, most respondents supported the text of a), b) and c) as written in the proposal. The eWG was split on its views on whether the text presented within d) should be retained, deleted, or modified.

#### **5.9.2 Additional Labelling Requirements – Provision 9.6.2**

Of the 18 eWG members who supported Option 2 for Section 9.6, 13 members supported the more detailed provision 9.6.2 (the second approach presented), with most supporting the text as proposed. It was suggested that the provision could however be rewritten so it was more succinct and to improve readability.

#### **5.9.3 Additional Labelling Requirements – Provision 9.6.3**

The majority of respondents commenting on provision 9.6.3 accepted the text proposed in square brackets. Additional Labelling Requirements – Provision 9.6.4

The majority of respondents who commented on provision 9.6.4 accepted the proposed text. It was the suggestion of one CMO that the following text be added to this provision which would be in line with EU legislation; **'and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used'**.

### Conclusion

Some modifications to the preferred approaches may be required to ensure that Section 9.6 is not more stringent than that required on the label of infant formula. The proposed new statement within provision 9.6.3 regarding not comparing product to breast milk is a repetition of the newly proposed 9.6.2.4 and should therefore not be included.

#### Recommendation 21:

The CCNFSDU agree to the following text for Section 9.6, that the Committee consider the text presented within the square brackets included within the individual provisions.

#### 9.6 Additional Labelling Requirements

**9.6.1** Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- {a) the words "important notice" or their equivalent;}
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- {c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.}

~~{d) the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.}~~

~~{9.6.2 The label shall have no pictures of infants and women nor any other picture[, ] or text[, ] which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might:~~

~~9.6.2.1 idealize the used of follow-up formula for older infants;~~

~~9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);~~

~~9.6.2.3 recommend or promote bottle feeding;~~

~~9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;~~

~~9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.}~~

**9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used. ~~[In addition, the product should not be compared to breast-milk].~~

**{9.6.4}** Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes[, **and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.**]

## 6 SCOPE AND LABELLING – YOUNG CHILDREN (12-36 MONTHS)

A total of 41 responses were received to the 2<sup>nd</sup> Consultation Paper on the Scope and Labelling of [name of product] for young children:

28 Codex Members (CM)

1 Codex Member Organisation (CMO) – representing 28 Members States

11 Codex Observers (CO)

For the analysis of submissions, one CM submitted a response that supported the position of the CMO. To avoid their response being counted twice, their response was taken account of when considering the position of the CMO. This approach resulted in the tally of responses from CMs being reduced to 27, equating to a total of 40 individual responses.



## 6.1 Classification of Product

As already mentioned within Section 6.1 of this paper, and as per [REP17/NFSDU](#) (para 116), the 2017 eWG was asked to consider the issue of 'whether the products should be considered breast-milk substitutes'. This has been considered by many eWG members when answering questions relating to the Scope, in particular when giving consideration to; if and how, the Standard could take into account any WHA resolutions and WHO policies. Many eWG members have also considered whether [name of product] for young children may be a breast-milk substitute as part of forming their position on additional labelling requirements and the definition of product.

It was interesting to note that in answering questions on the additional labelling requirements and on the definition of [name of product] for young children, 17 eWG members specifically expressed the view that [name of product] for young children is not a breast-milk substitute, whereas 14 members were of the view that [name of product] for young children is a breast-milk substitute, with six respondents to the 1<sup>st</sup> Consultation Paper either remaining silent on their position, or not articulating a definitive position. One CMO considered that clarifying within the Standard whether or not the product should be considered to be a breast-milk substitute is unnecessary, particularly in light of the different views on what a breast-milk substitute is, and provided that there is clear distinction from infant formula.

## 6.2 Scope – Individual provisions

### 6.2.1 Scope – Section 1.1

Within the 1<sup>st</sup> Consultation Paper, it was proposed that the product definition and the role of [name of product] in the diet of young children sit outside the Scope and be captured within Section 2.1 – Product Definition so as to avoid repetition. The following statement was therefore proposed for consideration by the eWG:

- 1.1** This section of the Standard [**Section B**] applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

Based on the comments received from the eWG members to the 1<sup>st</sup> Consultation Paper, a second option was presented for eWG consideration. The second option involves the inclusion of the statement; *It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)*.

#### eWG views

It was the preference of the eWG that the statement *It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)* not be included within Section 1.1 of the Scope for [name of product] for young children.

#### Conclusion

Noting the preference of the eWG and view of the Secretariat at CCNFSDU38, that the Scope should be a concise statement in accordance with the Procedural Manual, it is proposed that CCNFSDU adopt a clear and concise statement as to the food or foods to which the Standard is applicable for Section 1.1.

#### Recommendation 22:

That CCNFSDU agree to the following statement for Section 1.1:

- 1.1** This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

### 6.2.2 Scope – Section 1.2

In the 1<sup>st</sup> Consultation Paper, the following statement was proposed for Section 1.2. This approach aligns with the same provision within the Infant Formula Standard.

- 1.2** This section of the Standard contains compositional, quality and safety requirements for [name of product] for young children.

Whilst there was majority support from the eWG for this proposal and modified wording, it was suggested that in order to be comprehensive, the labelling provisions and methods of analysis should be added to this statement. The eWG was therefore asked to consider a revised statement with the following amendments contained within square brackets to ensure that Section 1.2 is comprehensive and accurately reflects the content of Section B of the Standard.

#### Scope – Section 1.2

- 1.1** This section of the Standard contains compositional, quality, [**and**] safety, [**labelling and analytical**] requirements for [name of product] for young children.

## eWG views

Whilst majority of eWG members supported the proposal as presented above, 12 eWG members raised concerns over the inclusion of 'analytical' within Section 1.2. One member country suggested that 'analytical' could be defined.

## Conclusion

Based on the views of the eWG, it is recommended that Section 1.2 of the Scope for [name of product] for young children be expanded to reference the labelling and analytical requirements within the Standard so that the statement is comprehensive and reflects the content of Section B of the Standard. It is worth noting that this proposed text is additional to that contained within the same provision of the Infant Formula Standard.

### Recommendation 23:

That CCNFSDU agree to the following statement for Section 1.2:

1.2 This section of the Standard contains compositional, quality, safety, {labelling and analytical} requirements for [name of product] for young children.

### 6.2.3 Scope – Section 1.3

As part of the first round of consultation, the eWG was asked if a statement similar to that contained within Section 1.3 of the Infant Formula Standard was necessary for [name of product] for young children, and if so, they were asked to comment on the following modified text for [name of product] for young children:

**1.3** Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for [marketing] **[being named]** as [infant formula] **[[name of product] for young children]**. ~~[No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.]~~

Whilst there was majority support for retaining a statement similar to that presented above, the eWG had mixed views as to the appropriate terminology to be used. The use of the term 'marketing' in this provision polarised the group. Apprehension over the inclusion of a reference to 'marketing' was expressed by many members as it was their view that the term 'marketing' is too broad, and may create confusion as it could be understood by some to also be interpreted as 'promotion'. Contrary to this view, others specifically supported the inclusion of the term 'marketing' within Section 1.3, with some of these members noting it would ensure consistency with the same section of the Infant Formula Standard. Several members who supported the inclusion of the term 'marketing' within Section 1.3 of the Scope, stated that this support was on the provision that the term be defined to provide clarity to this statement, and to avoid any confusion or misinterpretation. It was suggested a definition for 'marketing' could take the form of a footnote and the definition for marketing should include the sale and distribution of product, but should not extend to the promotion or advertising.

A scan of various definitions for 'marketing' revealed that 'marketing' has multiple definitions and interpretations globally, with differing approaches as to whether 'marketing' extends to the sale, distribution, promotion and/or advertising. It was therefore viewed that it would be problematic to define 'marketing' for the purposes of this Standard. Further to this, 'marketing' is not defined in the Infant Formula Standard. Recommending a definition of 'marketing' for inclusion in the Follow-up Formula Standard as proposed by several members in the form of a footnote, may therefore create a situation where this definition differs to what is considered to be 'marketing' in the Infant Formula Standard.

Based on comments received from the eWG to the first round of consultation, various modified options for the wording of Section 1.3 of the Scope for [name of product] for young children, without a reference to 'marketing' were presented to the eWG in the second round of consultation for their consideration. These were:

- OPTION 1: Only products that comply with the criteria laid down in the provisions of this section of this Standard **[should be presented as]** [name of product] for young children.
- OPTION 2: Only products that comply with the criteria laid down in the provisions of this section of this Standard **[may be presented as suitable for]** [name of product] for young children.
- OPTION 3: Only products that comply with the criteria laid down in the provisions of this section of this Standard **[would be accepted for being presented as]** [name of product] for young children.
- OPTION 4: Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for **[being named/called]** [name of product] for young children.

## eWG views

Based on the comments received from the eWG, Option 1 was the preferred approach, with two of the 17 eWG members who supported Option 1 suggesting that '*should be presented as*' be modified to read '*may be presented as*' and '*shall be presented as*'. One CMO suggested that the entire paragraph could be deleted altogether as the requirement contained within Section 1.3 is not present in other standards for foods for infants and young children (for example, CODEX STAN 74 – 1981 for *Processed Cereal-Based Foods for Infants and Young Children*). Further to this, the comment was made that the requirement appears more important in the Infant Formula Standard where it is accompanied by the additional requirement that '*No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life*'.

## Conclusion

Based on the views of the eWG, with respect to Section 1.3 and noting that there is majority support for a standard which clearly differentiates the different formula products from one another so as to avoid confusion and misuse of the respective products, it is recommended that Section 1.3 be retained for [name of product] for young children with the suggested text within Option 1 being the preferred approach. Consideration should however be given to the correct terminology. Whilst Option 1 uses '*should*', '*shall*' would be more consistent with the terminology used in the labelling section of the Standard. Option 1 was also the preferred approach for follow-up formula for older infants.

### Recommendation 24:

That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

- 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as} [name of product] for young children.

## 6.2.4 Scope – Section 1.4

As already mentioned under 6.2.4, at CCNFSDU36 and CCNFSDU38 it was discussed that the Scope and Labelling sections could include referencing relevant WHO documents and WHA resolutions on optimal infant and young child nutrition, and on the non-necessity of these products. Previous eWGs and the Committee have continued to recognise the relevance of WHA 39.28 and have agreed that follow-up formula is not considered nutritionally necessary in the diets of older infants and young children ([REP15/NFSDU](#), para 91).

Within the 2016 eWG there were differences in opinion as to which WHA resolutions and WHO policies should be referenced, or whether they should be referenced at all.

In the 1<sup>st</sup> Consultation Paper for 2017 on the Scope and Labelling aspects, the eWG were asked to consider if and which WHA resolutions and WHO policies are relevant to the *Standard for Follow-up Formula*, and whether these should be referenced in the Standard or whether specific provisions within the Standard, such as the labelling aspects can be drafted to reflect the intent of these resolutions and documents.

As a starting point for discussion, the below text which was modified from Section 1.4 of the current Infant Formula Standard was presented to the eWG:

- 1.4 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, [the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children] and [relevant] World Health Assembly resolution[s] [including WHA .....] [WHA54.2(2001).]

## eWG views

Of the 38 respondents to the 1<sup>st</sup> Consultation Paper, 23 eWG members (including 1 CMO) indicated their preference for referencing one or more WHA resolutions or WHO documents within the Standard for [name of product] for young children. Contrary to this view, 15 eWG members either indicated a preference for no reference at all (8 eWG members), a generic statement regarding the applicability of 'relevant' documents or resolutions without citing what these might be (2 eWG members), a specific request for exclusion of certain resolutions or documents and no comment on whether others should be referenced (2 eWG members), did not articulate a clear position or did not respond to the question (3 eWG members).

The WHO document cited by eWG members as being most relevant to [name of product] for young children was the 1981 [International Code of Marketing of Breast-milk Substitutes](#) (the WHO Code) with 21 eWG members supporting a reference within the Standard for [name of product] for young children. It is interesting to note, that whilst seven of these members supported a reference to the WHO Code, and its applicability to [name of product] for young children, the same seven members considered [name of product] for young children not to be a breast-milk substitute when responding to the question on Additional Labelling Requirements and articulating their preference to retain the statement that *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'* for [name of product] for young children.

Second to the WHO Code, 19 eWG members supported a specific reference to either the [WHO Guidance](#) on 'Ending inappropriate promotion of foods for infants and young children' and/or its Resolution ([WHA69.9](#)) in the Standard for [name of product] for young children. Within the eWG, some members suggested the Follow-up Formula Standard specifically reference WHA 69.9, others preferred that consideration is given to the Resolution and associated Technical Guidance document by incorporating certain recommendations within the Labelling section of the Standard, rather than a specific reference within the Standard.

In addition to the above documents, 18 eWG members (including 1 CMO) cited the [WHO Global Strategy for Infants and Young Children](#) as being relevant and requiring referencing within the Standard for [name of product] for young children, with ten of these members also citing the relevant resolution WHA 54.2. Two additional members cited WHA 54.2 only.

There were various reasons presented by those members who are of the view that WHA resolutions and WHO documents should not be referenced in the Standard which included:

- The purpose of WHO documents and WHA resolutions is to help determine public health policies. These documents should provide direction and guidance for governments in developing their own national public health policies in accordance with their national context.
- The review of the Standard can take in to consideration the policies of WHO without the need to specifically reference individual documents or resolutions.
- Future amendments to WHO/WHA documents should not be automatically adopted as part of this Standard without first being considered by the Committee as to the relevance of these amendments. A process for reviewing any referenced document is essential if WHO/WHA documents are to be cited within the Standard.
- Not all sections of the noted WHA resolutions and WHO documents are applicable to the Standard and to [name of product] for young children, or to individual national contexts, leading to confusion if they were to be included.

### Conclusion

Within the eWG there were more respondents supporting reference to one or more WHO/WHA documents within the Follow-up Formula Standard for [name of product] for young children than there were respondents against any form of reference. Strong positions were presented for and against referencing WHO/WHA documents and determination of which documents may be appropriate and applicable proved to be challenging.

The Codex Secretariat and WHO has worked to progress this issue and find a workable solution. There is general agreement from WHO and the Secretariat that the Preamble include reference to relevant documents, noting that this approach to the Preamble would replace the need to list or reference specific resolutions or documents within the different sections of the Standard itself, as the Preamble is applied to the Standard as a whole and applies to both product groups. This approach would make provision 1.4 of the Scope redundant.

#### Recommendation 25:

That CCNFSDU agree:

- to include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper.
- to delete provision 1.4 for [name of product] for young children from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.

### 6.3 Labelling – Introductory Paragraph

The Labelling section (Section 9) of the current *Standard for Follow-up Formula* sets out labelling requirements for follow-up formula products. In the introduction to Section 9 both the Codex Infant Formula and Follow-up Formula Standards refer to other general Codex labelling standards and guidelines which are applicable to these respective products.

Both the Codex Infant and Follow-up Formula Standards specifically state that the requirements of the *General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)) apply. The Infant Formula Standard also specifies that the requirements of the *Guidelines on Nutrition Labelling* ([CAC/GL 2-1985](#)) and the *Guidelines for Use of Nutrition and Health Claims* ([CAC/GL 23-1997](#)) apply to infant formula and formula for special medical purposes for infants. The *Guidelines for Use of Nutrition and Health Claims* do not permit nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation ([CAC/GL 23-1997](#)).

Members of the 2017 eWG were asked if they supported the inclusion of an introductory paragraph to the Labelling section for [name of product] for young children, similar to that presented in Section 9 – Labelling, of the Infant Formula Standard which states that the requirements within the following Codex texts are applicable:

*General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)*

*Guidelines on Nutrition Labelling (CAC/GL 2-1985)*

*Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)*

#### eWG views

There was almost unanimous support for the inclusion of an introductory paragraph to the labelling section for [name of product] for young children which includes a reference to applicability of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985). Comment was however made that the NRV's included in the *Guidelines on Nutrition Labelling* are for the general population and are therefore not appropriate for young children, and as such, these may need to be adapted for the target audience.

Whilst the 1<sup>st</sup> Consultation Paper did not explicitly ask if the *Guidelines for Use of Nutrition and Health Claims* should be referenced in an introductory paragraph to the Labelling section for [name of product] for young children, as nutrition and health claims were explored separately (see discussion below), several members specifically commented that they supported its inclusion in the introductory paragraph.

#### 6.3.1 Ingredient and nutrient declarations/claims

The 2017 eWG was tasked by the Committee to examine the promotional aspect of follow-up formula for older infants and [name of product] for young children, as well as misleading claims (REP17/NFSDU para.118).

The purpose of declaring nutrition information is to provide caregivers with adequate information to be able to make informed decisions about the appropriate use of these products. The *Declaration of Nutritive Value* and the *List of Ingredients* are the primary elements on follow-up formula that are currently permitted as means of providing nutrition information to caregivers.

Previous eWG's have not explored whether claims should be '*specifically provided for*' in the Follow-up Formula Standard, nor whether permissions for the provision of information, including declarations about nutrients, ingredients, the nutrition content, and any health effects should extend beyond what is currently permitted on follow-up formula as part of the ingredient list or declaration of nutritive value.

The 2017 eWG were asked to comment on whether voluntary declarations about nutrients and ingredients, including declarations about the nutrition content and any health effects, should be permitted on the label of [name of product] for young children. Any such permission would extend beyond what is currently allowed and required on the label as part of the ingredient list or declaration of nutritive value. Electronic working group members were asked to consider what type of declaration or claim should be permitted, how they might be regulated, and whether any permission should be for mandatory nutrients and/or optional nutrients and ingredients.

It is worth noting that *Nutrition Claim* means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals, and includes nutrient contents claims, nutrient comparative claims, and non-addition claims. *Health Claim* means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health, and includes nutrient function claims, other function claims and reduction of disease risk claims.

### **eWG views expressed in the first round of consultation**

In response to the first round of consultation, 17 members specifically articulated a position whereby they do not support voluntary declarations or claims about nutrients or ingredients on the label of [name of product] for young children. Concern was expressed that such declarations have the potential to confuse and undermine breastfeeding and many were of the view that such declarations are a form of advertising or promotion.

Contrary to this view, 13 eWG members specifically supported voluntary declarations on [name of product] for young children. Five of these members stated that permissions for voluntary declarations or claims should be in accordance with relevant Codex Standards or national legislation. Whilst there were some members who supported declarations for both mandatory and optional nutrients and ingredients, others were of the view that voluntary declarations for optional ingredients only should be permitted. Whilst not all of those respondents that supported voluntary declarations, commented on what type(s) of claims should be permitted, only two members explicitly supported health claims. Comments received in support of some form of voluntary declaration included; declarations should only be permitted for nutrients or ingredients present in quantities higher than 15% of the daily reference intake, content claims should be permitted provided the nutrient is addressed in the Standard, nutritional content or presence/absence claims for optional ingredients and nutrients should be permitted for those with established minimum, maximum or concentration levels.

Claims and declarations on the label of [name of product] for young children continues to be a very contentious issue with no clear direction on what approach should be taken. Deciding on what constitutes a 'voluntary' declaration and under what circumstances these might be permitted is problematic and challenging, posing more questions than answers:

- How do you determine levels for claims such as 'low in lactose' when cut offs vary globally (just like they do with gluten)?
- Should claims about nutrients that are intrinsically present in ingredients be permitted – i.e. contains lactoferrin/ with added lactoferrin? Would levels need to be established in order for such claims to be made?
- If the Standard were to permit content claims for optional nutrients and ingredients, should minimum levels be established with the food containing at least this amount of the optional addition in order for a claim to be made? How should the Standard accommodate this approach to declarations for optional nutrients/ingredients if the list is not exhaustive?
- Adding to the complexity is the absence of NRV's in Codex for this age group – making % claims difficult.

Due to the lack of consensus and the complexity of issues associated with establishing parameters for different types of claims and declarations for [name of product] for young children, and in accordance with the views of the eWG, it was proposed in the second round of consultation that the same approach as that taken in the Infant Formula Standard (and that recommended for follow-up formula for older infants) should also be applied to [name of product] for young children. That approach would see the inclusion of a reference within the introductory paragraph for the Labelling section (Section 9) to the applicability of the recommendations in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) to [name of product] for young children. It would also include a statement that the prohibition on the use of nutrition and health claims contained within the Guidelines exists except where '*specifically provided for in relevant Codex Standards or national legislation*'.

This approach whilst still allowing for declarations and claims if included in future revisions of relevant Codex Standards, or in national legislation, would be the most pragmatic approach to what continues to be an issue of contention and divergent views, and is consistent with the current Codex approach.

### **eWG views expressed during the second round of consultation**

There was majority support for the proposed approach that a reference to the applicability of the recommendations in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) to [name of product] for young children be included within the introductory paragraph of the Labelling Section. Several members were of the view that such declarations have the potential to undermine breastfeeding and may constitute advertising.

That being said, four eWG members agreed with the proposal to reference the *Guidelines for Use of Nutrition and Health Claims* but suggested a modified approach to allow for voluntary declarations about nutrients and ingredients on [name of product] for young children. The modified proposal suggested that:

- The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)), the *Guidelines on Nutrition Labelling* ([CAC/GL 2-1985](#)) and the *Guidelines for Use of Nutrition and Health Claims* ([CAC/GL 23-1997](#)) apply to [name of product] for young children.
- Taking in to account paragraph 1.4 of the *Guidelines for Use of Nutrition and Health Claims*, nutrition and health claims may be permitted for [name of product] for young children provided that they have been demonstrated in rigorous studies with adequate scientific standards.
- The use of nutrition claims based on Nutrient Reference Values (NRVs) be permitted as soon as NRVs specifically for young children are adopted by Codex.

Additional comments received included; the need for further consideration to be given to how consumers might be able to identify and differentiate key nutrients in [name of product] for young children, and if nutrient declarations or claims are to be permitted for these products, these should be equivalent to claims that core food groups can make for this age group, and nutrition claims should be permitted, but not function claims.

### Conclusion

It would appear that the current wording of section 1.4 of the Scope for the *Guidelines for Use of Nutrition and Health Claims* which states that; '*Nutrition and health claims shall not be permitted for foods for infants and young children **except where specifically provided for in relevant Codex standards or national legislation***' (emphasis added) would allow for national authorities to include provisions for claims (that align with national nutritional policies) on [name of product] for young children in their own national legislation. It is therefore recommended that the proposed approach be adopted and a position be maintained whereby nutrition and health claims are not permitted on [name of product] for young children unless specifically provided for in relevant Codex Standards or national legislation.

#### Recommendation 26:

That CCNFSDU agree to the following introductory paragraph to the Labelling Section for [name of product] for young children (Section B):

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)), the *Guidelines on Nutrition Labelling* ([CAC/GL 2-1985](#)) and the *Guidelines for Use of Nutrition and Health Claims* ([CAC/GL 23-1997](#)) apply to [name of product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

### 6.3.2 Nutrient Reference Values (NRVs) for infant and young children

The 2017 eWG were also asked to consider whether nutrition claims (not health claims) should be revisited after the completion of NRV's for the older infant and young child age group (6 – 36 months). **Nutrition claim** means any representation which states, suggests or implies that a food has particular nutritional properties including, but not limited to, the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

#### eWG views

There was majority support for revisiting nutrition claims for [name of product] for young children after the completion of NRVs for older infants and young children. Contrary to this view, eight members specifically commented that claims of any sort, should not be permitted on [name of product] for young children.

Other comments included that any discussion on claims should be restricted to nutrition content claims for optional ingredients only.

Several members who supported revisiting nutrition claims after the completion of NRVs expressed the position that they did not want this proposal to impact on the progress of revising the Standard. The suggestion was made that the Committee may want to consider the appropriateness of nutrient content claims once the nutrient composition of [name of product] for young children is finalised. Furthermore, it was suggested that the Committee consider an approach for nutrition claims that does not require the reopening of the Standard if the claim can be substantiated by a credible scientific body, such as JEMNU, and after a complete scientific review. The Standard could include a provision for the use of nutrition claims based on NRVs when they become available and are adopted by Codex, rather than the Standard needing to be revised at this time.

## Conclusion

Previous eWGs have considered the role of [name of product] for young children in the diets of this age group and have recognised that such products are often used as a substitute, alternative or replacement for cows' milk, and could supplement the diet to provide those nutrients which are of key global concern for this age group. In order to progress the essential composition of [name of product] for young children, the Committee (at CCNFSDU38) refined the principles for selecting which nutrients must be mandatory additions. These were principles were agreed to be;

Evidence to support:

- Contribution to the nutritional needs of young children where the nutrient is widely inadequate; and/or
- Contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or
- The nutritional quality and integrity of product to ensure nutritional safety.

If NRV's are established for young children, it may be reasonable for the Committee to give consideration to an approach whereby nutrition claims on [name of product] for young children be permitted to allow for communication of the composition of this product and the key nutrients present.

### Recommendation 27:

That CCNFSDU note the preference of the eWG for revisiting nutrition claims on [name of product] for young children should NRVs be established and adopted by Codex for this age group.

That CCNFSDU agree that the progress of reviewing this Standard should not be delayed and that any consideration of NRVs (if established for this age group) and the purpose of such NRVs in the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985), including the need to consider whether any labelling provisions within Codex standards for foods for infants and young children need to be revisited if NRVs are adopted by Codex, should form part of the ToR for a NRV working group.

Noting that the Committee cannot foresee the outcome of any work on NRVs for this age group should it proceed, it is recommended that the status quo for nutrition (and health) claims, that is that the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation, remain.

## 6.4 Labelling – Name of the Product

Based on comments received from eWG members to the 1<sup>st</sup> Consultation paper, the below drafting of Section 9.1 was recommended for [name of product] for young children.

The main concern expressed by the group was the wording of 9.1.4. It was suggested that the wording of 9.1.4 should be modified to include milk from animals/sources other than cows. Several members asked that consideration be given to including provisions for labelling when soy or other protein sources (such as goats' milk) are used, noting that this could also be covered by provision 9.1.3. Some suggested that 9.1.4 could actually be deleted as this section becomes redundant if the sources of protein(s) are indicated as per provision 9.1.3. Others were however supportive of retaining provision 9.1.4 and labelling which specifically indicates when cows' milk (or other protein sources such as goat or soy) are the only source of protein present in the product.

It was proposed that the wording of 9.1.4 be modified to state; *If cows' milk is the only source of protein, the product may be labelled "(Name of Product) for Young Children Based on Cows' Milk [Protein]"*. It was thought that *'based on cows' milk protein'* was a more factual reflection of the composition as most of the components in a formula based on cows' milk protein are often not derived from cows' milk, therefore *'based on cows' milk'* is not correct and adequate.

Comment was received that suggested in order to be able to use the qualifier *'based on cows' milk'*, the provision should require more than only the origin of the protein. It was therefore suggested that inclusion of a provision similar to Section 3.3.1.2 of the current Follow-up Formula Standard be considered as qualification for when [name of product] for young children may be labelled *'based on cows' milk'*.

Section 3.3.1.2 of the current Follow-Up Formula Standard states that follow-up formula based on milk must represent a minimum of 90% of the total protein derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk.

In addition to the above comments, one CMO asked that 9.1.2 be modified to include a reference to *'regional'* usage after *'national'* in order to take into account the situation of the EU.



The below modified drafting was presented to the eWG for their consideration at the second round of consultation:

Name of the Product	
<b>9.1</b>	<b>The Name of the Product</b>
<b>9.1.1</b>	The text of the label and all other information accompanying the product shall be written in the appropriate language(s).
<b>9.1.2</b>	The name of the product shall be <i>[Name of Product] for Young Children</i> as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national <b>[or regional]</b> usage.
<b>9.1.3</b>	The sources of protein in the product shall be clearly shown on the label.
<b>9.1.4</b>	If <del>cow</del> 's <b>[name of animal/plant-based]</b> milk is the only source of protein, the product may be labelled '[Name of Product] for Young Children Based on <del>cow</del> 's <b>[name of animal/plant based]</b> milk <b>[protein]</b> '.
	<b>OR</b>
	[If 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content, the product may be labelled '[Name of Product] for Young Children based on [name of animal] Milk].
	<b>OR</b>
	[Delete 9.1.4, covered by 9.1.3]
<b>9.1.5</b>	A product which contains neither milk nor any milk derivative <b>[shall] [may]</b> be labelled "contains no milk or milk products" or an equivalent phrase.

#### eWG views

In relation to the above proposed drafting, the 2017 eWG had the following views:

##### 6.4.1 Name of Product – Provision 9.1.2

There was majority support for adopting the proposed text with the inclusion of 'regional' within provision 9.1.2 to take account of the situation within the EU.

##### 6.4.2 Name of Product – Provision 9.1.4

Within provision 9.1.4, whilst the first approach proposed was the preferred option, there was nearly as many in favour of deleting provision 9.1.4 as it is in effect covered by provision 9.1.3. In relation to the first approach, many members who supported this proposal suggested modifications to the wording or suggested the provision be split in to two so that one statement relates to animal milks or animal protein and the second for products based on plant protein. Furthermore, many members specifically commented that the term 'milk' should only be used in association with the 'name of animal' and not as 'plant-based milk'.

Several eWG members also commented that individual amino acids may need to be added to [name of product] for young children to reach adequate protein quality. As such, it was the view of these members that some guidance may be required, for example within a footnote, to clarify that the labelling provision based on 'only source of protein' as presented and proposed within 9.1.4 would not preclude the addition of these amino acids.

##### 6.4.3 Name of Product – Provision 9.1.5

Within the second round of consultation, it was noted that within provision 9.1.5, the Infant Formula Standard uses the term 'shall' whereas the current Follow-up Formula Standard uses the term 'may' within the same provision. Working group members were asked to comment on their preferred terminology. There was majority support for deleting 'may' and removing the square brackets from 'shall'.

#### Conclusion

As there was majority support within the 2017 eWG for the wording proposed for 9.1, 9.1.1, 9.1.2 and 9.1.3, it is recommended that these provisions be adopted as is without modification. Based on the views of the eWG, the following recommendation is made in relation to the remaining provisions within Section 9.1. This is the same recommendation as that being made for Section 9.1 for follow-up formula for older infants.

**Recommendation 28:**

That CCNFSDU agree to the following text for Section 9.1 – The Name of the Product, and select its preferred option for provision 9.1.4, including the text within the square brackets.

**9.1 The Name of the Product**

**9.1.1** The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

**9.1.2** The name of the product shall be *[Name of Product] for Young Children* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

**9.1.3** The sources of protein in the product shall be clearly shown on the label.

**9.1.4** OPTION 1: Split provision 9.1.4 into two:

**9.1.4(a)** If [name of animal] milk is the only source of protein[\*], the product may be labelled '[Name of Product] for Young Children based on [name of animal] milk [protein]'.

**9.1.4(b)** If [name of plant] is the only source of protein[\*], the product may be labelled '[Name of Product] for Young Children based on [name of plant] [protein]'.

[\* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

**OR**

OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

**9.1.5** A product which contains neither milk nor any milk derivative [shall] ~~[may]~~ be labelled "contains no milk or milk products" or an equivalent phrase.

**6.5 Labelling – List of Ingredients**

In the 1<sup>st</sup> Consultation Paper, the Chairs proposed that provisions 9.2.1 and 9.2.2 (relating to the List of Ingredients) of the Infant Formula Standard be adopted for [name of product] for young children.

There was almost full support from the eWG for adopting the List of Ingredient provisions within the Infant Formula Standard for [name of product] for young children. It was requested that some flexibility be given to provision 9.2 to accommodate national or regional regulations. Further to this, it was suggested that the functional use, and optionally the INS number, for additives should also be declared.

It was also commented that the provision should specifically require the declaration of optional ingredients, to ensure relevant compositional information is provided for use by both health care professionals and consumers.

As a result of eWG feedback to the 1<sup>st</sup> Consultation Paper, the following modified drafting for Section 9.2 – List of Ingredients was presented to the eWG for their consideration.

**List of Ingredients****9.2 List of Ingredients**

**9.2.1** A complete list of ingredients [**including optional ingredients**] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

**9.2.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. [**Food additives may also optionally declare the INS number**].

**eWG views**

With respect to provision 9.2.1, it was the preference of the eWG to delete the proposal to specifically include reference to optional ingredients. It was the view of many that the proposed text in square brackets is redundant as it is captured by the requirement within the provision for a '*complete list of ingredients*' with extends to optional ingredients.

In relation to provision 9.2.2, there was majority support for adopting the draft text as proposed, including the text within the square brackets.

## Conclusion

Based on the views of the eWG, it would appear that the majority of respondents do not see a need for provision 9.2.1 to specifically state that optional ingredients also need to be included in the ingredients list. Further to this it would appear that the majority of respondents are not opposed to including the statement that in addition to the specific name, food additives may also declare the INS number. This aligns with the preferred approach for the List of Ingredients for follow-up formula for older infants.

### Recommendation 29:

That CCNFDU agree to the following text for Section 9.2 – List of Ingredients.

#### 9.2 List of Ingredients

**9.2.1** A complete list of ingredients [~~including optional ingredients~~] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

**9.2.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. {Food additives may also optionally declare the INS number}.

## 6.6 Labelling – Declaration of Nutritive Value

In the 1<sup>st</sup> Consultation Paper, the Declaration of Nutritive Value clause of the Infant Formula Standard was modified to reference [name of product] for young children and the text ‘grammes’ was replaced with ‘grams’. This modified text was presented to the eWG for their comment.

### eWG views expressed in the first round of consultation

In relation to the declaration of nutritive value for [name of product] for young children, the below comments were received from the eWG. Whilst there was majority support (21 eWG members) for the drafting text as presented in the 1<sup>st</sup> Consultation Paper, the following comments were received from eWG members.

Six eWG members considered that the declaration of nutrition information per 100ml in ready for use product, or as prepared according to the directions on the label to be of more value to consumers than per 100g of powder. Further to this, five eWG members considered ‘per serve’ amounts to be of value to consumers and requested that the presentation of nutritive values per serve also be provided for in Section 9.3.

Additionally, one member considered that modelling the declaration of nutritive value of [name of product] for young children on how it is presented on infant formula has the potential to mislead consumers. It was suggested that labelling should be consistent with other conventional beverages or other complementary foods for young children so that consumers could make easy comparisons between products. Another eWG member who is of the view that [name of product] for young children is not a breast-milk substitute, proposed that Section 3.4 in the *Guidelines on Nutrition Labelling* could be applied to this product.

It was noted that the *Guidelines on Nutritional Labelling* permit nutrient information to be expressed as percentages of the NRV where an NRV has been established. The suggestion was made that CCNFDU should therefore progress the establishment of NRV’s for older infants and young children.

The suggestion was made that some flexibility be given to Section 9.3 to accommodate national or regional regulations.

Based on the comments received from eWG members to the 1<sup>st</sup> Consultation Paper, the below drafting for Section 9.3 for [name of product] for young children was presented at the second round of consultation for further consideration by the eWG.

### Declaration of Nutritive Value

#### 9.3 Declaration of Nutritive Value

The declaration of nutrition information [**for [name of product] for young children**] shall contain the following information which should be in the following order:

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [**as well as**] [**or**] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold **[as well as]** ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per **[serving size and/or per]** 100 kilocalories (or per 100 kilojoules) is permitted.

#### eWG views expressed in the second round of consultation

Many respondents commented that it was their view that the declaration of nutrients per 100ml of ready to use product to be most valuable for consumers. The comment was made that to leave the choice between declaring the nutritive value per 100 grams or per 100 millilitres of the food as sold or per 100 millilitres of the food ready for use, up to manufacturers, has the potential to create confusion for consumers when comparing products.

There was also widespread support for the proposal to allow for the optional declaration of nutrients per serving.

#### Conclusion

Based on the views of the eWG, it is recommended that 'as well as' be adopted as the preferred text. Further to this requirement, the declaration of nutrients per serving should also be provided for within provision 9.4, as an optional addition. A similar provision has not be included for follow-up formula for older infants.

#### Recommendation 30:

That CCNFSDU agree to the following drafting text for Section 9.3 – Declaration of Nutritive Value for [name of product] for young children.

#### 9.3 Declaration of Nutritive Value

The declaration of nutrition information ~~{for [name of product] for young children}~~ shall contain the following information which should be in the following order:

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per ~~{serving size and/or per}~~ 100 kilocalories (or per 100 kilojoules) is permitted.

### 6.7 Labelling – Date Marking and Storage Instructions

The *General Standard for the Labelling of Pre-packaged Foods* ([CODEX STAN 1-1985](#)), is currently under review. This includes the date labelling conventions being finalised by the Codex Committee on Food Labelling (CCFL). Based on the comments received from the eWG and noting the need to be consistent with the outcome of any decisions made at CCFL, the below modified text which aligns with the wording of the date marking sections put forward at CCFL43 be adopted for [name of product] for young children. It is understood that within the *Proposed Draft Revisions to the General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) (*At Step 5 as of September 2017*) only the exemption section remains in square brackets. It is however important to note that as the full standard has not yet been completed it is possible that other areas could still change.

#### Date Marking and Storage Instructions

#### 9.4 Date Marking and Storage Instructions

**9.4.1** The **“Best Before Date” or “Best Quality Before Date”** date of minimum durability (preceded by the words “best before”) shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

**9.4.2** In addition to the date, any special conditions for the storage of the food shall be indicated if [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

#### **Recommendation 31:**

As this paper was written prior to CCFL44, it is recommended that CCNFSDU agree to modify the above text (as necessary) and adopt any changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting.

### **6.8 Labelling – Information for Use**

During the first round of consultation, the eWG were asked to consider if the Follow-up Formula Standard requires the level of prescription contained within section 9.5 of the Infant Formula Standard, and whether different approaches might be required for the different products; infant formula, follow-up formula for older infants, and [name of product] for young children.

It is worth noting that *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) which covers the ‘*production, preparation and use of products available in powdered form, referred to as Powdered Formulae (PF)*’ currently forms part of Section 6 – Hygiene of both the current Follow-up Formula Standard and the Infant Formula Standard. It is therefore proposed that the revised Follow-up Formula Standard should align with the approach taken in the Infant Formula Standard and any reference to this Code be included within Section 8 – Hygiene, of the revised Follow-up Formula Standard rather than replicating it within Section 9.5.

As part of the first round of consultation, the eWG were asked if any of the Information for Use provisions in the Infant Formula Standard should be adopted for [name of product] for young children, and whether there are any additional Information for Use provisions that should be considered by the eWG for inclusion in the Standard for [name of product] for young children.

The current Information for Use provisions in the Infant Formula Standard are as follows:

#### **9.5 Information for Use**

**9.5.1** Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

**9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.

**9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product.

**9.5.4** The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

**9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.

By comparison, the current Follow-up Formula Standard contains a single provision that relates to the safe preparation, storage and use of product, in addition to two other 'information for use' provisions relating to the appropriate age of introduction of follow-up formula, and the need for infants and children fed follow-up formula to receive other complementary foods in addition to the formula.

In the 1<sup>st</sup> Consultation Paper, the eWG were asked to consider whether the following approaches in relation to Section 9.5 for [name of product] for young children be adopted;

- Re-word the title of Section 9.5 of the Follow-up Formula Standard to; Information for [Use] ~~Utilization~~, to align with the Infant Formula Standard.
- A requirement for the labelling of [name of product] for young children to have a statement that [name of product] for young children shall not be introduced before 12 months of age.
- A requirement for the labelling of [name of product] to have information that young children shall receive other foods in addition to the product.

### **eWG views expressed in the first round of consultation**

There was full support from the eWG to change the title of Section 9.5 to Information for Use.

There was also majority support for the proposal that a requirement for the labelling of [name of product] for young children include a statement that [name of product] for young children shall not be introduced before 12 months of age. It was the view of many that such a statement would assist in distinguishing this product from follow-up formula for older infants and infant formula. Further to this, comment was made that the composition of [name of product] for young children is nutritionally inadequate and unsuitable for infants, and as such this statement is essential to communicate to the consumer the appropriate age of use. Such a statement would also compliment Recommendation 4 of the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children which states that products should include the appropriate age of introduction of the food. Recommendation 4 also supports a statement on the importance of continued breastfeeding for up to two years of age or beyond and the importance of not introducing complementary foods before six months of age. Three eWG members commented that the labels of [name of product] for young children should therefore include a statement regarding the importance of continued breastfeeding in line with Recommendation 4.

Two eWG members suggested the addition of a statement that communicates that '*These products should be used as part of a balanced diet*' and one CM suggested the statement '*Do not use as a sole source of nutrition*' be required on the label of [name of product] for young children.

The eWG was divided in its views on whether a requirement for the labelling of [name of product] for young children should include information that young children shall receive other foods in addition to the [name of product] for young children. Twenty members were supportive of such an approach, with one CM commenting that consumers do not clearly distinguish the different formula products, therefore this information would help guide consumers as to the appropriate use of product and clarify the consumer group for whom the product is intended.

Opposed to this approach were 10 eWG members who were of the view that such a statement was 'redundant' or 'unnecessary' for the age group of young children and this product. Comment was made that the diets of young children would already be diversified with the introduction of complementary feeding from the age of around six months. One CO suggested a recommendation that the product label could communicate that [name of product] for young children should only be used as part of a mixed diet. This could be achieved by also including a requirement for the recommended amount for consumption (i.e. 1-2 cups per day) to be on the label. One CMO commented that further consideration should be given to a requirement for the label of [name of product] for young children to have a statement about the intended use of product.

In response to the request for comment on whether any of the provisions contained within Section 9.5 of the Infant Formula Standard should be adopted for [name of product] for young children 22 eWG members supported adoption of all of the provisions contained within Section 9.5 of the Infant Formula Standard with some minor modifications suggested.

Contrary to this approach, others were of the view that not all provisions contained within Section 9.5 of the Infant Formula Standard should be adopted for [name of product] for young children. Five members commented that as [name of product] for young children would be consumed as part of a mixed diet when young children are also eating other general purpose foods, the information for use provisions could be reduced (or modified) from what is required for infant formula. One CM who is of the view that [name of product] for young children is not a breast-milk substitute suggested an alternative approach whereby the specifications in the *General Standard for Labelling of Pre-packaged Foods* (CODEX STAN 1 – 1985) could be applied. Two other members suggested that the EU food regulations regarding labelling could be applied to [name of product] for young children as the product forms part of a mixed diet. Two CM specifically commented that a requirement for ‘warnings’ or ‘health hazards’ is not necessary on a food product which would be consumed in addition to other foods. In relation to provision 9.5.3, two members suggested that the requirement for *‘the label to carry clear graphic instructions illustrating the method of preparation of the product’* could be an optional provision according to the country where the product is sold.

Most respondents considered that there is no need for additional provisions for [name of product] for young children in addition to those already discussed above. It was however suggested that a statement advising that pictures of bottles should not be permitted on labels of [name of product] for young children should be included. It was the view of these members that this would be an additional differentiating factor between product for young children and infant formula and follow-up formula for older infants. Other suggestions included; that a statement relating to the non-sterile nature of the product be included on the label, and a statement that the product is not necessary for the growth and development of young children should be on the label.

Based on the comments received from eWG members to the 1<sup>st</sup> Consultation Paper, various options for Section 9.5 were presented to the eWG for their consideration. In line with the content of Section 9.5 – Information for Use of the current Follow-up Formula Standard, it was proposed that the provisions contained within Section 9.5 relate to how the product should be used, including the safe preparation, use and storage of product, the appropriate age from which the product can be consumed, and the requirement for product to be ‘used’ in addition to other foods. As an alternative to itemising the ‘information for use’ labelling requirements and presenting these as individual provisions (Option 1), a second option was also prepared (Option 2) where these requirements are merged in to two paragraphs. It was thought this approach may assist in avoiding any repetition and duplication. It was also considered that ‘Information for Use’ provisions or statements should not be more stringent for [name of product] for young children, than what is proposed for follow-up formula for older infants, and what is currently required for infant formula.

The two options are replicated below:

Information for Use	
<b>Option 1:</b>	
<b>9.5</b>	<b>Information for Use</b>
<b>9.5.1</b>	Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
<b>9.5.2</b>	Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula [product] remaining after feeding should be discarded, shall appear on the label [ <del>and in any accompanying leaflet</del> ].
<b>9.5.3</b>	The label shall carry clear graphic instructions illustrating the method of preparation of the product. <b>[Pictures of feeding bottles are not permitted on labels of [name of product] for young children.]</b>
<b>9.5.4</b>	[The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use].
<b>9.5.5</b>	Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [ <del>and in any accompanying leaflet</del> ].
<b>[9.5.6</b>	<b>The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a balanced diet.]</b>

<b>Option 2:</b>	
<b>9.5</b>	<b>Information for Use</b>
	<b>[The following 'Information for use' requirements are mandatory provisions that must appear on the label of (name of product) for young children;</b>
<b>9.5.1</b>	<b>a statement that [name of product] for young children should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation, adequate directions for the appropriate preparation, handling, storage and use of product, in accordance with Good Hygienic Practice. The label shall also carry clear graphic instructions illustrating the method of preparation of the product, noting that pictures of feeding bottles are not permitted.</b>
<b>9.5.2</b>	<b>a statement that the product shall not be introduced before 12 months of age and should be used as part of a balanced diet.]</b>

### **eWG views expressed in the second round of consultation**

There was majority support for Option 1 with one CMO stating that they could support either approach.

#### **6.8.1 Information for Use – Provision 9.5.1**

No comments were sort on provision 9.5.1, however three members suggested modifications relating to hygiene and water temperature. These modifications would require more detail than what is currently required for infant formula. As such, they are not included in the recommendation. It would appear that the majority of the eWG are happy to adopt provision 9.5.1 as it is currently written. It is worth noting that for follow-up formula for older infants, one CM provided alternative wording for this provision to make it more succinct. This alternative wording is being put forward in the recommendation for Committee consideration. For consistency, the same proposal will be presented for [name of product] for young children. The alternative wording is:

- 9.5.1** [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [~~Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.~~] Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

#### **6.8.2 Information for Use – Provision 9.5.2**

There was majority support for replacing 'formula' with 'product' and for deleting the previously proposed text in the square brackets.

#### **6.8.3 Information for Use – Provision 9.5.3**

Amongst eWG members, there was a preference for including a statement that pictures of feeding bottles are not permitted on the label of [name of product] for young children. It was suggested by one CM that this requirement would better sit within provision 9.6.1 where prohibited images, text or illustrations are captured.

#### **6.8.4 Information for Use – Provision 9.5.4**

There was majority support for retaining the text in square brackets.

#### **6.8.5 Information for Use – Provision 9.5.5**

There was majority support for deleting the strikethrough text in square brackets.

#### **6.8.6 Information for Use – Provision 9.5.6**

Of those eWG members who supported Option 1 and who commented on provision 9.5.6 there was majority support for adopting the proposed text contained within the square brackets. There were however some suggestions for modifications to the text. Several members favoured replacing 'balanced' with 'diversified'. Others indicated a preference for stating that the product is not to be used as a sole source of nutrition. It could be viewed that this is implicit in the requirement for the label of [name of product] for young children to state that [name of product] for young children should be used as part of a balanced/diversified diet.



## Conclusion

Based on the views of the eWG, it is recommended that the text of 9.5.1 be modified, the requirement for information to be included in any accompanying leaflet be deleted, that a prohibition on pictures of feeding bottles be included under Section 9.6 rather than Section 9.5 and that the Committee consider the text contained within the square brackets within provision 9.5.6.

### Recommendation 32:

That CCNFSDU agree to the following text for Section 9.5 for [name of product] for young children and comment on the text still remaining in square brackets.

#### 9.5 Information for use

**9.5.1** [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

**9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula~~ [product] remaining after feeding should be discarded, shall appear on the label.

**9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product. ~~[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]~~

**9.5.4** ~~[The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use].~~

**9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

**[9.5.6]** The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] ~~[balanced]~~ diet.]

## 6.9 Labelling – Additional Labelling Requirements

The Infant Formula Standard contains additional labelling requirements which are largely based on Article 4 of the WHO Code. By comparison, the current Follow-up Formula Standard only has one additional requirement which is that the *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'*.

In the 1<sup>st</sup> Consultation Paper, the 2017 eWG were asked to consider if this requirement under section 9.6 of the current Follow-up Formula Standard should be retained for [name of product] for young children. Alternatively, the Standard could refer to the presentation of [name of product] for young children. The eWG must therefore consider whether [name of product] for young children should be permitted to be 'presented' as a substitute for breast-milk.

The eWG were also asked to consider if any of the additional labelling information provisions contained within the Infant Formula Standard are applicable to [name of product] for young children and whether there are additional requirements that should be considered for [name of product] for young children.

The current provisions in the Infant Formula Standard are as follows:

### 9.6 Additional Labelling Requirements

**9.6.1** Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- a) the words "important notice" or their equivalent;
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.

**9.6.2** The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

- 9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used.
- 9.6.4** Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.
- 9.6.5** The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

### **eWG views expressed in the first round of consultation**

In the 1<sup>st</sup> Consultation Paper, eWG members were asked if the statement in the current Follow-up Formula Standard that reads *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'* should be retained for [name of product] for young children. Seventeen eWG members specifically commented that the statement should be retained, 11 members supported deletion of the statement with a further two CM's suggesting the statement be modified to say that [name of product] is a breast-milk substitute. Six eWG members remained silent, and two members were of the view that requirement for such a statement is unnecessary, with one CMO commenting that the statement adds to the confusion given the different views on what constitutes a breast-milk substitute.

From those in favour of retaining this statement, most specifically stated that they consider [name of product] for young children not to be a breast-milk substitute. Many commented that the proposed composition of [name of product] for young children is very different to breast-milk therefore this product should not be represented as a breast-milk substitute. Of those in favour of deleting this statement, several cited WHA69.9 and the associated WHO technical guidance as clarification of what should be considered to be a breast-milk substitute.

Electronic working group members were then asked to comment on whether the individual provisions (9.6.1, 9.6.2 and 9.6.3) within Section 9.6 of the Infant Formula Standard should be adopted for [name of product] for young children.

#### **6.9.1 Additional Labelling Requirements - Provision 9.6.1**

Within the eWG there was majority agreement that the labelling of [name of product] for young children should not discourage breastfeeding. Whilst 15 eWG members supported adoption of provision 9.6.1 for [name of product] for young children (with or without some minor modifications) others agreed that it is appropriate to include a statement regarding breastfeeding within Section B of the Standard, but this need not be as prescriptive as the provision 9.6.1 requirements for infant formula. Several members commented that whilst a provision similar to that presented in 9.6.1 (b) is appropriate for [name of product] for young children, 9.6.1 (a) and (c) are not needed on product for the young child age group. Furthermore, several members did not support the inclusion of provision 9.6.1 for [name of product] for young children on the basis they do not consider [name of product] to be a breast-milk substitute.

Comment was made by one CMO that as agreed to by the 2016 eWG, [name of product] for young children has a very different role in the diet compared to follow-up formula for older infants, especially taking in to consideration that after one year of age cows' milk consumption is also recommended – the 2017 eWG must therefore consider if all the Section 9.6 provisions are applicable to this product.

#### **6.9.2 Additional Labelling Requirements - Provision 9.6.2**

Fifteen eWG members agreed with the wording and inclusion of provision 9.6.2, with two of these members commenting that they would support it only if 'infant formula' is replaced with the name adopted for [name of product] for young children.

Nine eWG members considered provision 9.6.2 unnecessary for [name of product] for young children, with several explicitly expressing the view they do not support its adoption as they do not consider the product to be a breast-milk substitute.

#### **6.9.3 Additional Labelling Requirements - Provision 9.6.3**

There was majority support within the 2017 eWG for adopting provision 9.6.3 of the Infant Formula Standard (as written) for [name of product] for young children.

#### **6.9.4 Additional Labelling Requirements - Provision 9.6.4**

In the 1<sup>st</sup> Consultation Paper, it was proposed that provision 9.6.4 be deleted and consideration of this requirement be covered under Section 9.5. There was majority support from the eWG for this proposal.

### 6.9.5 Additional Labelling Requirements - Provision 9.6.5

In the 1<sup>st</sup> Consultation Paper, it was proposed that a provision similar to that contained within provision 9.6.5 of the Infant Formula Standard be adopted for [name of product] for young children. The following wording was proposed: ***Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula [for older infants], [[name of product] for young children], and formula for special medical purposes.***

There was majority support from the eWG for this proposal and the need to be able to clearly differentiate the different formula products from one another so as to avoid confusion and misuse of the respective products.

Comment was received from several members who supported this proposal noting that it is anticipated that this differentiation between products will also be achieved due to the adoption of distinctly different product names.

Based on eWG feedback and comments to the 1<sup>st</sup> Consultation Paper, two options were presented on how the 'additional labelling provisions' might be captured in the Standard for [name of product] for young children. Option 1 merges provisions 9.6.1, 9.6.2 and 9.6.3 (Option 1). Alternatively, individual provisions could be retained, and various options for how these are drafted are presented below within Option 2. It would be reasonable to expect that any additional labelling requirements for [name of product] for young children should not be more stringent than what is required on the label of infant formula or follow-up formula for older infants. Given the diverse views of the eWG, Option 1 would allow for some level of flexibility whereby national authorities could further describe the level of detail required on the label of [name of product] for young children with respect to not discouraging breastfeeding and any further limitations on graphics or text.

Given the differing views on what constitutes a breast-milk substitute, it was considered that the approach proposed by the CMO (representing 28 member countries), whereby a statement such as, *'products covered by this standard are not breast-milk substitutes and shall not be represented as such'* and which is included in the current Follow-up Formula Standard, is unnecessary. As a compromise way of moving forward it has been recommended that this statement not be retained in the Standard for [name of product] for young children. This approach does not prejudice or determine whether the product should be considered a breastmilk substitute or not.

The two options that were presented to the eWG at the second round of consultation are replicated below:

Additional labelling requirements	
<b>Option 1:</b> Merges 9.6.1, 9.6.2, 9.6.3 (to become 9.6.1), deletes 9.6.4, and presents modified wording (and renumbering to become 9.6.2) for the original provision 9.6.5:	
<b>9.6 Additional Labelling Requirements</b>	
<b>[9.6.1</b>	<b>The label of [name of product] for young children shall have no image, text or representation that could undermine or discourage breastfeeding or which idealises the use of (name of product) for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.]</b>
<b>[9.6.2]</b>	Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes.
<del>[9.6.4]</del>	<del>Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.]</del>
<b>Option 2:</b> Retains individual provisions for 9.6.1, 9.6.2, 9.6.3, deletes provision 9.6.4, and presents modified wording (and renumbering to become 9.6.4) for the original provision 9.6.5:	
<b>9.6 Additional Labelling Requirements</b>	
<b>9.6.1</b>	Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
[a)	the words "important notice" or their equivalent;]
b)	the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

(c)	a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]
(d)	<b>the statement; ‘The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding’.</b> ]
<b>OR</b>	
<b>[9.6.1 The label of [name of product] for young children should not discourage breastfeeding. It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond.]</b>	
<b>AND</b>	
<b>9.6.2</b>	The label shall have no pictures of infants [ <del>and women</del> ] nor any other picture or text which idealizes the use of [ <del>infant</del> ] [follow-up] formula [for older infants].
<b>OR</b>	
<b>[9.6.2</b>	The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might:
<b>9.6.2.1</b>	suggest use for infants under the age of 6 months (including references to milestones and stages);
<b>9.6.2.2</b>	recommend or promote bottle feeding;
<b>9.6.2.3</b>	undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;
<b>9.6.2.4</b>	convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]
<b>AND</b>	
<b>9.6.3</b>	The terms "humanized", "maternalized" or other similar terms shall not be used. <b>[In addition, the product should not be compared to breast-milk].</b>
<b>AND</b>	
<b>[9.6.4]</b>	Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes.
<del><b>[9.6.4]</b></del>	<del>Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.]</del>

### eWG views expressed in the second round of consultation

Twenty one eWG members (including one CMO representing 28 member states) preferred the approach presented as Option 1 for the Additional Labelling Requirements for [name of product] for young children. Sixteen members favoured Option 2.

Of those members supporting Option 1, the majority supported the wording proposed for provision 9.6.1. As discussed under section 7.8 – Information for Use (of this paper), specifically 7.8.3, it has been recommended that a prohibition on pictures of feeding bottles be included under Section 9.6 rather than Section 9.5 of the Standard.

With respect to provision 9.6.2 proposed under Option 1, it was suggested by one CMO that the provision be extended to include the text ‘... and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used’. It was suggested that this addition would assist in reinforcing the provision which communicates that a clear distinction between products is important.

### Conclusion

It is recommended that Option 1 be put forward for Committee agreement.

### Recommendation 33:

That CCNFSDU agree to the following text for Section 9.6 for [name of product] for young children and that the Committee consider the text presented within the square brackets included within the individual provisions.

## 9.6 Additional Labelling Requirements

**[9.6.1]** The label of [name of product] for young children shall have no image, text or representation **[,including pictures of feeding bottles,]** that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.}]

**[9.6.2]** Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used].**

## 7 DEFINITIONS

The 2017 eWG has been tasked with finalising the product definitions contained within section 2.1 – Product Definition. As per Appendix III, Part I of the Report of the 37<sup>th</sup> Session of CCNFSDU ([REP16/NFSDU](#)), the Committee has already agreed to the below definitions contained within section 2.2 – Other Definitions, of the Follow-up Formula Standard.

### 2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age.

2.2.3 The term **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

### 7.1 Product definition – follow-up formula for older infants

Definition 2.1.1 is yet to be finalised for both product categories. The 1<sup>st</sup> Consultation Paper presented the following definitions for follow-up formula for older infants for the eWG to consider:

#### Definition of follow-up formula for older infants

Original proposal:

- **Follow-up formula for older infants** means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced.

Proposals from Committee Members:

- **Follow-up formula for older infants** means a product, [in liquid or powdered forms], intended for use [as a total or partial substitute for breast-milk given] as the liquid part of the diet for older infants when complementary feeding is introduced.
- **Follow-up formula for older infants** means a product intended for use as ~~the liquid part of the diet for older infants when complementary feeding is introduced~~ [a substitute for human milk in helping to meet the normal nutritional requirements of older infants]
- **Follow-up formula for older infants** means a product intended for use as the liquid part of the diet for older infants [as either a breast milk substitute or a replacement for infant formula] when complementary feeding is introduced.
- **Follow-up formula for older infants** means a product [specially manufactured] ~~intended~~ for use as the liquid part of the diet for older infants when [appropriate] complementary feeding is [progressively] introduced
- **Follow-up formula for older infants** means a product intended for use as the liquid part of ~~the~~ [a diversified] diet for older infants when complementary feeding is introduced

#### eWG views expressed in the first round of consultation

During the first round of consultation the eWG was split in its views on whether the definition should reference what follow-up formula for older infants is replacing in the diet (i.e. breastmilk and/or infant formula). Members were split between the first of the new proposals as presented above and the last two proposals or a modification of these.

The terms ‘*specially manufactured*’ or ‘*specially formulated*’ were considered by some to be an important element of the definition. Many provided the justification that the product must meet special requirements, that it is more appropriate than ‘*intended*’, and that the wording ‘*specially manufactured*’ aligns with the Infant Formula Standard.

There was some support for ‘*diversified*’ or ‘*progressively diversified*’ to be included in the definition in relation to the diet of older infants.

Some members noted that it would be incorrect to define the product as ‘*the liquid part*’ of the diet for older infants and that ‘*a liquid part*’ should rather be used, as water is also gradually introduced in the diet of older infants together with complementary feeding, and older infants may also consume other liquids such as breast-milk and infant formula. It was also mentioned by one member that the product is a principal liquid part of the diet for older infants and that this be included in the definition.

The suggestion was made by two members to not include in the definition the wording ‘*when complementary feeding is introduced*’.

One CMO supported a broad and simple definition, which would cover both follow-up formula for older infants and [name of product] for young children: “*Follow-up formula means a product intended for use as a liquid part of the progressively diversified diet for older infants, when complementary feeding is introduced, and for young children*”.

Based on the responses from the eWG members and the further suggestions made in response to the definition proposals in the 1<sup>st</sup> Consultation Paper, the comments were consolidated and the proposals refined to two options for the definition of follow-up formula for older infants which include elements of the proposals from the first consultation round that received the most support. These two new proposals were presented to the eWG for further consideration and are replicated below:

Definition of follow-up formula for older infants
<p>New proposals:</p> <ul style="list-style-type: none"> <li>• <i>Follow-up formula for older infants means a product, specially manufactured for use [as a substitute for breast-milk / or a replacement for infant formula] as a liquid part of the diet for older infants when complementary feeding is introduced.</i></li> <li>• <i>Follow-up formula for older infants means a product, specially manufactured for use as a liquid part of [a progressively / diversified] diet for older infants when complementary feeding is introduced.</i></li> </ul>

### eWG views expressed in the second round of consultation

During the second round of consultation, 15 eWG members selected the first proposal presented above. Contrary to this, 16 eWG members and one CMO supported the second proposal, or a variation of this definition i.e. a definition which does not reference what follow-up formula for older infants is replacing in the diet (i.e. breast-milk and/or infant formula). It was noted that the preference of the CMO was for one broad simple definition covering both follow-up formula for older infants and [name of product] for young children as is the case in the current Follow-up Formula Standard. That being said, it was the view of the CMO that if the group agrees to two separate definitions, it is their preference for a definition which does not include a reference to what follow-up formula for older infants would replace as is the approach taken in EU legislation (Article 2(2)(d) of Regulation (EU) No 609/2013 which states that ‘*follow-on formula means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principle liquid element in a progressively diversified diet of such infants*’.

### Conclusion

Noting the view of 16 eWG members and one CMO (representing 28 member states) for a definition which does not include a reference to what follow-up formula for older infants would replace in the diet of such infants (i.e breast-milk and/or infant formula) it is recommended that the following definition be put forward for consideration by the Committee:

<p><b>Recommendation 34:</b></p> <p>That CCNFSDU agree to the following definition for follow-up formula for older infants:</p> <p><b>Follow-up formula for older infants</b> means a product, specially manufactured for use as a liquid part of <del>the</del> <b>[a progressively / diversified]</b> diet for older infants when complementary feeding is introduced.</p>
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## 7.2 Product definition – [Name of product] for young children

The eWG members were asked to select a preferred definition for [name of product] for young children from the list provided in the 1<sup>st</sup> Consultation Paper, or provide a modified definition for consideration by the eWG.

The options proposed in the 1<sup>st</sup> Consultation Paper were:

Original proposal:

- **[Name of Product] for young children** means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.

Proposals from eWG members:

- **[Name of Product] for young children** means a product [specifically manufactured] intended for use as a liquid part of the progressively diversified diet [in order to contribute to the nutritional needs of young children] when nutrient intakes may not be adequate to meet the nutritional requirements. ~~of young children.~~
- **[Name of Product] for young children** means a product intended for use as a [substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a] liquid part of the progressively diversified diet. ~~when nutrient intakes may not be adequate to meet the nutritional requirements of young children.~~
- **[Name of Product] for young children** means a product ~~intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children~~ [that is not necessary but may be used as part of a child's progressively diversified diet. It should not share branding with infant formula, nor be promoted, since this would undermine breastfeeding and the consumption of culturally appropriate and more nutritious bio-diverse family foods.]

It was noted that some of the above definition proposals included the term 'specifically manufactured' which is not consistent with the product definition proposals for follow-up formula for older infants and the product definition in the Infant Formula Standard where 'specially manufactured' is used. It was acknowledged that the relevant proposals for product for young children should also have used the term 'specially manufactured'.

#### **eWG views in the first round of consultation**

There were some eWG members that supported more than one proposal presented to the group. The numbers below reflect that and thus do not add up to the total number of responses received.

The definition that received the most support (11 members) was:

- **[Name of Product] for young children** means a product [specifically manufactured] intended for use as a liquid part of the progressively diversified diet [in order to contribute to the nutritional needs of young children] when nutrient intakes may not be adequate to meet the nutritional requirements. ~~of young children.~~

There was further support for a modified version of this definition in which 'progressively' was deleted or 'in order to contribute to the nutritional needs of some subgroups of young children' was inserted.

The second most supported (8 members) option was:

- **[Name of Product] for young children** means a product intended for use as a [substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a] liquid part of the progressively diversified diet. ~~when nutrient intakes may not be adequate to meet the nutritional requirements of young children.~~

Five members commented that the square brackets around 'substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a' should be removed as the text is not optional in the definition.

The original proposal received support from five eWG members. Four eWG members proposed definitions which included that the product 'should not share branding with infant formula, nor be promoted, since this would undermine breastfeeding and the consumption of culturally appropriate and more nutritious bio-diverse family foods'. On the contrary, three members commented that the definition should limit itself to the target population and the appropriate use in the diet.

Fifteen eWG members did not support any of the proposals provided, with 12 presenting new or modified proposals. Of the modified proposals two included that product for young children is used as a substitute for breast milk. Three eWG members wanted the definition to include that the product is not necessary and four proposals included the format of the product 'in liquid or powdered forms'.

One CMO supported a broad and simple definition, which would cover both follow-up formula for older infants and [name of product] for young children: “*Follow-up formula means a product intended for use as a liquid part of the progressively diversified diet for older infants, when complementary feeding is introduced, and for young children*”.

With regards to the sentence “*when nutrient intakes may not be adequate to meet the nutritional requirements*” in the definition proposals, one CM and one CMO expressed the view that including it can lead to the interpretation that a progressively diversified diet will not be sufficient to meet the nutritional requirements of young children and that the product would be necessary for this purpose, noting that the Committee has already agreed the product is not considered nutritionally necessary.

This sentence was also deleted in the second most popular definition, supported by eight eWG members, and it was not part of eight out of the 12 modified proposals suggested by the eWG members. On the other hand, it was included in definitions supported or proposed by 17 members.

Some members proposed simpler, shorter definition options such as *[Name of product] for young children means a product specifically manufactured for use as a liquid part of the diversified diet for young children* or *[Name of Product] for young children means a product specifically formulated and manufactured for use as a liquid part of the progressively diversified diet of young children*.

Noting that ‘*specifically manufactured*’ should have been ‘*specially manufactured*’, and noting that there was strong support from the majority for the format of the product to be included in the Scope Section 1.1, the following refined definitions were prepared based on eWG comments for further consideration at the second round of consultation.

#### Definition of [name of product] young children

New proposals:

- ***[Name of Product] for young children means a product specially manufactured for use as [a liquid] part of the [progressively] [diversified] diet [[in order to contribute to the nutritional needs of young children] [when nutrient intakes [may not be / are not likely to be] adequate to meet nutritional requirements].***
- ***[Name of Product] for young children means a product specially manufactured for use as a substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a liquid part of the progressively diversified diet.***
- ***[Name of product] for young children means a product specially [formulated and] manufactured for use as a liquid part of the [progressively] [diversified] diet of young children.***

#### eWG views expressed in the second round of consultation

Of the 37 responses received on the definition, the majority of these (28 members) supported either the first or third proposal, that being a definition which does not define the product as a breast-milk substitute. When all responses from those selecting the first or third proposal are considered, the following was noted;

- Unanimous support for ‘a liquid part’
- Majority support for ‘diversified diet’ (25/28)
- 18/28 supporting the inclusion of ‘progressively’
- Respondents were split on whether ‘formulated’ should be included within the third definition, with one CMO suggesting it be deleted.

#### Conclusion

As the eWG was split between the first and third proposals, it is recommended that the following definition be considered, noting the majority support to adopt the text; *use as a liquid part* and *diversified diet* as well as the preference for *may not be adequate* rather than *are not likely to be adequate*.

#### Recommendation 35:

That CCNFSDU consider the following proposal for the definition of (name of product) for young children, including the text in square brackets.

***[Name of product] for young children means a product specially [formulated and] manufactured for use as a liquid part of the [progressively] [diversified] diet of young children [in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements].***



## 8 NAME OF PRODUCTS

### 8.1 Name of product for older infants

The 1<sup>st</sup> Consultation Paper proposed that the name *Follow-up Formula for Older Infants* be adopted as the name of product for older infants.

#### eWG views

There was almost unanimous support for the adoption of the name *Follow-up Formula for Older Infants* for name of the product for older infants. Given the strong support for the name *Follow-up Formula for Older Infants*, by the 2017 eWG during the first round of consultation no further comment was sought during the second round of consultation.

#### Recommendation 36:

That CCNFSDU agree to adopt the name ***Follow-up Formula for Older Infants*** as the name of product for the 6 – 12 month age group (older infants).

### 8.2 Name of product for young children

Many members of the 2016 eWG commented that product for young children should not be considered a 'formula' as this confuses [name of product] for young children with formula marketed and suitable for use by infants in the first year of life.

In considering the name of the product for young children, the following parameters/issues have been identified either by the Committee at CCNFSDU38, or within the 2016 eWG:

- product for young children should not be considered a 'formula'
- product for young children must have a distinctly different name to follow-up formula for older infants
- the name of the product for young children needs to include plant-based products, noting that these products cannot use the denomination of 'milk' since these are not based on milk from cows or other animals.

The eWG members were asked in the 1<sup>st</sup> Consultation Paper to identify if there are further issues or parameters that the eWG should consider when deciding on the name of product for young children.

The eWG members were also asked to indicate a preferred name from the following list or provide an alternative for consideration by the eWG keeping in mind the issues mentioned above:

- *Fortified milk product for young children*
- *Processed milk product for young children*
- *Drink for young children*
- *Fortified milk for young children*
- *Formulated milk powder for young children*
- *Young child milk-based (or plant based) beverage*

#### eWG views expressed in the first round of consultation

Comment was received that most of the proposals do not fulfil the parameters identified by the eWG, one of which is that plant-based products cannot use the denomination of 'milk' since they are not based on milk from animals. On the other hand the rationale for this parameter was queried when there are many 'milks' on the market today that are not based on milk from animals, such as soy milk, almond milk or rice milk, and there is even a Codex Standard dealing with 'Coconut Milk and Coconut Cream'.

None of the proposals for the name of product for young children presented in the first round of consultation received significant support with 29 new or modified proposals provided by the eWG. It is interesting to note that the majority of these contained the words 'milk' or 'milk-based', 'formulated', and 'young child/children'. The term 'fortified' was supported by six eWG members and 'supplementary' was included in four of the new proposals.

A number of members either provided two options for a name (including options for either 'milk-based' or 'plant based') or commented that whilst plant-based products cannot be classified as milks, a name could be adopted where either 'milk-based' or 'plant-based' could be used depending on the source of protein. It is noted that this will potentially be covered under section 9.1 where the following options are being provided to the Committee for their consideration:

**9.1.4**            OPTION 1:     Split provision 9.1.4 into two:

**9.1.4(a)**        If [name of animal] milk is the only source of protein[\*], the product may be labelled '(Name of Product) for Young Children based on [name of animal] milk [protein]'.

**9.1.4(b)**        If [name of plant] is the only source of protein[\*], the product may be labelled '(Name of Product) for Young Children based on [name of plant] [protein]'.

[\* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]

**OR**

OPTION 2:     Delete provision 9.1.4 as it is covered by 9.1.3

One CO raised a concern for the use of 'milk product' in the name, as the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) defines 'milk product' as 'a product obtained by any processing of milk, which may contain food additives, and other ingredients functionally necessary for the processing' and Codex Milk Products standards cover everything from milk powders to yoghurts, cheese, butter and cream. Using the term 'milk' in the name is also problematic as the *General Standard for the Use of Dairy Terms* also stipulates that:

*“4.6.3 In respect of a product which is not milk, a milk product or a composite milk product, no label, commercial documents, publicity material or any form of point of sale presentation shall be used which claims, implies or suggests that the product is milk, a milk product or a composite milk product, or which refers to one or more of these products.*

*4.6.4 However, with regard to products referred to in Section 4.6.3, which contain milk or a milk product, or milk constituents, which are an essential part in terms of characterization of the product, the term “milk”, or the name of a milk product may be used in the description of the true nature of the product, provided that the constituents not derived from milk are not intended to take the place, in part or in whole, of any milk constituent. For these products dairy terms may be used only if the consumer would not be misled. If however the final product is intended to substitute milk, a milk product or composite milk product, dairy terms shall not be used.”*

The same member commented that given the above and considering the variation in the composition of the products covered by this Standard, using the term “fortified milk” would be misleading.

It was noted that the term 'formulated' is used by Codex in relation to complementary foods (for example in the title of the document *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991)) and that this would serve as a useful precedent for its use in (name of product) for young children. Another member commented that the name should include formulated, rather than fortified or processed, since these products are specifically manufactured. On the other hand 'formulated' was also mentioned to be too close to 'formula', which should be avoided.

'Supplementary' in the name was supported by three members in their proposals noting that these products are regarded supplementary as they are not necessary but can be beneficial in contributing to the nutritional needs of young children when nutrient intakes may not be adequate.

The term “fortified” was mentioned to be already in use for other products and to be generally associated with fortification of products with vitamins and/or minerals (e.g. fortified milks for general population), whereas [name of product] for young children also has essential fatty acids and other nutrients added.

Whilst the name proposal 'Drink for young children' was criticized for not giving any indication that the product is a nutritious drink and could be understood by parents being a water-base, fruit-base or even a soft drink, the comment was also made that name should be as neutral as possible with no benefit implied as it is accepted that these products are not necessary.

Based on the comments received in the first consultation round, proposals for the name of product for young children were narrowed down to the following options for eWG consideration:

Name of product young children
<p>New proposals:</p> <ul style="list-style-type: none"> <li>• <b>[Formulated / Supplementary] milk-based (or plant-based) [drink / beverage] for young children</b></li> <li>• <b>[Formulated / Supplementary] [drink / beverage] for young children [based on source of protein]</b></li> </ul>

- **[Formulated / fortified] [drink / beverage] for young children [milk-based or plant-based]**
- **Young child milk-based (or plant-based) [formulated / supplementary] [drink / beverage]**

### eWG views expressed in the second round of consultation

From the responses received on the name of product for young children, it was noted that there is a clear preference to use 'drink' over 'beverage' and for 'formulated' over 'supplementary' within the name. There was also majority support for a name which allows for 'milk-based' or 'plant-based' to be used in the name of the food.

### Conclusion

To avoid duplication, it is recommended that the source of protein in relation to the name of the product be covered within Section 9.1 as a separate labelling provision, and for the name to therefore be simple. Section 9.1 permissions (if adopted) will allow for the name of the product to be further qualified with respect to the protein source.

#### Recommendation 37:

That CCNFSDU agree to either of the following two names for product for young children.

- Formulated drink for young children
- Young child formulated drink

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## Proposed Draft Standard

Please note that text presented in *blue italics* reflects the recommendations in Appendix I. All other text has already been agreed to (held at Step 4).

### PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)

#### [PREAMBLE]

*The Codex Alimentarius Commission acknowledges the need to [protect and support / recognize] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.*

*This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).*

## SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

### 1 [SCOPE]

- 1.1 *This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.*
- 1.2 *This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.*
- 1.3 *Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as] Follow-up Formula for Older Infants.*

### 2 DESCRIPTION

#### 2.1 Product Definition

- 2.1.1 *[Follow-up formula for older infants means a product, specially manufactured for use as a liquid part of ~~fa~~ progressively ~~diversified~~] diet for older infants when complementary feeding is introduced.]*
- 2.1.2 Follow-up formula [*for older infants*] is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

#### 2.2 Other Definitions

- 2.2.1 The term **infant** means a person of not more than 12 months of age.
- 2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age.

### 3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

#### 3.1 Essential composition

- 3.1.1 Follow-up formula [*for older infants*] is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.

- 3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy
- 3.1.3 Follow-up Formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL) <sup>1</sup>, as appropriate.

#### a) Protein <sup>2), 3), 4)</sup>

Unit	Minimum	Maximum	GUL
g/100 kcal	<del>[1.8]</del> [1.6] <sup>5), 6)</sup>	3.0	-
g/100 kJ	<del>[0.43]</del> [0.38] <sup>5), 6)</sup>	0.72	-

<sup>2)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>3)</sup> For an equal energy value the formula must contain an available quantity of each essential and semiessential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

<sup>4)</sup> Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

<sup>5)</sup> The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows' *[or non-goats']* milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of [2.25 g/100 kcal (0.54 g/100 kJ)] applies.

<sup>6)</sup> ~~Follow-up formula based on non-hydrolysed milk protein containing [1.61 – 1.8 g] protein/100 kcal should be clinically evaluated by a competent national and/or regional authority. Follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal should be clinically evaluated]~~

<sup>6)</sup> *Follow-up formula based on non-hydrolysed milk protein containing [less than 1.8 g protein/100 kcal (0.43 g protein/100 kJ)] and follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal (0.54 g protein/100 kJ)] should be clinically evaluated by a competent national and/or regional authority.]*

#### b) Lipids

##### Total Fat <sup>7), 8)</sup>

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.1	1.4	-

<sup>7)</sup> Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

<sup>8)</sup> Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

##### Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	72	-	335

<sup>1</sup> Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of older infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in follow-up formula for older infants should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-up formula for older infants or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

**$\alpha$ -Linolenic acid**

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	N.S.*	-
mg/100 kJ	12	N.S.	-

\*N.S. = not specified

**Ratio linoleic acid/  $\alpha$ -Linolenic acid**

Min	Max
5:1	15:1

**c) Carbohydrates****Available carbohydrates <sup>9)</sup>**

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

<sup>9)</sup> Lactose and glucose polymers should be the preferred carbohydrates in formula based on cow's milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.

**d) Vitamins****Vitamin A**

Unit	Minimum	Maximum	GUL
$\mu$ g RE <sup>10)</sup> /100 kcal	75	180	-
$\mu$ g RE <sup>10)</sup> /100 kJ	18	43	-

<sup>10)</sup> expressed as retinol equivalents (RE)

1  $\mu$ g RE = 3.33 IU Vitamin A = 1  $\mu$ g trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

**Vitamin D**

Unit	Minimum	Maximum	GUL
$\mu$ g <sup>11)</sup> /100 kcal	1.0	3.0	-
$\mu$ g <sup>11)</sup> /100 kJ	0.24	0.72	-

<sup>11)</sup> Calciferol. 1  $\mu$ g calciferol = 40 IU vitamin D.**Vitamin E**

Unit	Minimum	Maximum	GUL
mg $\alpha$ -TE <sup>12)</sup> /100 kcal	0.5 <sup>13)</sup>	-	5
mg $\alpha$ -TE <sup>12)</sup> /100 kJ	0.12 <sup>13)</sup>	-	1.2

<sup>12)</sup> 1 mg  $\alpha$ -TE (alpha-tocopherol equivalents) = 1 mg d- $\alpha$ -tocopherol

<sup>13)</sup> Vitamin E shall be at least 0.5 mg  $\alpha$ -TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg  $\alpha$ TE /g linoleic acid (18:2 n-6); 0.75  $\alpha$ -TE/g  $\alpha$ -linolenic acid (18:3 n-3); 1.0 mg  $\alpha$ -TE/g arachidonic acid (20:4 n-6); 1.25 mg  $\alpha$ -TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg  $\alpha$ -TE/g docosahexaenoic acid (22:6 n-3).

**Vitamin K**

Unit	Minimum	Maximum	GUL
$\mu$ g /100 kcal	4	-	27
$\mu$ g /100 kJ	1.0	-	6.5

**Thiamin**

Unit	Minimum	Maximum	GUL
$\mu$ g /100 kcal	60	-	300
$\mu$ g /100 kJ	14	-	72

**Riboflavin**

Unit	Minimum	Maximum	GUL
$\mu$ g /100 kcal	80	-	500
$\mu$ g /100 kJ	19	-	119

**Niacin** <sup>14)</sup>

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	360

<sup>14)</sup> Niacin refers to preformed niacin

**Vitamin B<sub>6</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8.4	-	41.8

**Vitamin B<sub>12</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.024	-	0.36

**Pantothenic acid**

Unit	Minimum	Maximum	GUL
µg /100 kcal	400	-	2000
µg /100 kJ	96	-	478

**Folic acid**

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	50
µg /100 kJ	2.4	-	12

**Vitamin C** <sup>15)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 <sup>16)</sup>
mg /100 kJ	2.4	-	17 <sup>16)</sup>

<sup>15)</sup> expressed as L-ascorbic acid

<sup>16)</sup> This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

**Biotin**

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	0.4	-	2.4

**e) Minerals and Trace Elements****Iron** <sup>17)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	2.0	-
mg /100 kJ	0.24	0.48	-

<sup>17)</sup> For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies.

**Calcium**

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	180
mg /100 kJ	12	-	43



**Phosphorus**

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 <sup>18)</sup>
mg /100 kJ	6	-	24 <sup>18)</sup>

<sup>18)</sup>This GUL should accommodate higher needs with Follow-up formula based on soy protein isolate.

**Ratio calcium/phosphorus**

Min	Max
1:1	2:1

**Magnesium**

Unit	Minimum	Maximum	GUL
mg /100 kcal	5	-	15
mg /100 kJ	1.2	-	3.6

**Sodium**

Unit	Minimum	Maximum	GUL
mg /100 kcal	20	60	-
mg /100 kJ	5	14	-

**Chloride**

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	160	-
mg /100 kJ	12	38	-

**Potassium**

Unit	Minimum	Maximum	GUL
mg /100 kcal	60	180	-
mg /100 kJ	14	43	-

**Manganese**

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.0	-	100
µg /100 kJ	0.24	-	24

**Iodine**

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	60
µg /100 kJ	2.4	-	14.3

**Selenium**

Unit	Minimum	Maximum	GUL
µg /100 kcal	2	-	9
µg /100 kJ	0.48	-	2.2

**Copper <sup>19)</sup>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	120
µg /100 kJ	8.4	-	29

19) Adjustment may be needed in these levels for Follow-up formula made in regions with a high content of copper in the water supply.

### Zinc <sup>20)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

20) For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

## 3.2 Optional Ingredients

**3.2.1** In addition to the compositional requirements listed under 3.1.3 Section A, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

**3.2.2** When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.

**3.2.3** The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added.

### Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	3	-

### Total nucleotides

Levels may need to be determined by national authorities.

### Docosahexaenoic acid <sup>21)</sup>

Unit	Minimum	Maximum	GUL <del>[to be fixed after the fat content has been agree upon]</del>
mg /100 kcal	-	-	<del>30]</del>
mg /100 kJ	-	-	<del>7.9]</del>

<sup>21)</sup> If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, a minimum level of ~~[20 mg/100 kcal]~~ *[13 mg/100 kcal (3.1 mg/100 kJ)]* should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

### Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	50
mg /100 kJ	-	-	12

### Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	40
mg /100 kJ	-	-	9.6

### L-carnitine

Levels may need to be determined by national authorities.

**L (+) lactic producing cultures**

Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final formula product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

**9. [LABELLING]**

*The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.*

**9.1 The Name of the Product**

*9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).*

*9.1.2 The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national {or regional} usage.*

*9.1.3 The sources of protein in the product shall be clearly shown on the label.*

*9.1.4 OPTION 1: Split provision 9.1.4 into two:*

*9.1.4(a) If [name of animal] milk is the only source of protein[\*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].'*

*9.1.4(b) If [name of plant] is the only source of protein[\*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of plant] [protein].'*

*[\* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]*

**OR**

*OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3*

*9.1.5 A product which contains neither milk nor any milk derivative {shall} {may} be labelled "contains no milk or milk products" or an equivalent phrase.*

**9.2 List of Ingredients**

*9.2.1 A complete list of ingredients {including optional ingredients} shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.*

*9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. {Food additives may also optionally declare the INS number}.*

**9.3 Declaration of Nutritive Value**

*The declaration of nutrition information {for follow-up formula for older infants} shall contain the following information which should be in the following order:*

- d) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- e) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold ~~{as well as}~~ ~~{or}~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- f) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

#### 9.4 Date Marking and Storage Instructions

- 9.4.1** The **"Best Before Date" or "Best Quality Before Date"** ~~date of minimum durability (preceded by the words "best before")~~ shall be declared by the day, month and year ~~in uncoded numerical sequence~~ except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] will suffice. ~~The month may be indicated by letters in those countries where such use will not confuse the consumer. [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]~~

*In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.*

- 9.4.2** In addition to the date, any special conditions for the storage of the food shall be indicated ~~#~~ [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

*Where practicable, storage instructions shall be in close proximity to the date marking.*

#### 9.5 Information for Use

- 9.5.1** [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

- 9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~{product}~~ remaining after feeding should be discarded, shall appear on the label.

- 9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product.

- 9.5.4** The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

- 9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

- ~~**9.5.6** The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, ~~{is not to be used as a sole source of nutrition}~~ and that older infants should receive complementary foods in addition to the product.~~

#### 9.6 Additional Labelling Requirements

- 9.6.1** Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- ~~f~~a) the words "important notice" or their equivalent;

- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- {c} a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]
- ~~{d} the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.]~~
- ~~{9.6.2} The label shall have no pictures of infants and women nor any other picture[,] or text[,] which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might:~~
- ~~9.6.2.1 idealize the used of follow-up formula for older infants;~~
- ~~9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);~~
- ~~9.6.2.3 recommend or promote bottle feeding;~~
- ~~9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;~~
- ~~9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]~~
- 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. ~~{In addition, the product should not be compared to breast-milk}.~~
- ~~{9.6.4} Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.]~~

**SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN****1 [SCOPE]**

- 1.1 *This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.*
- 1.2 *This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for [name of product] for young children.*
- 1.3 *Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as} [name of product] for young children.*

**2 DESCRIPTION****2.1 Product Definition**

- 2.1.1 **[Name of product] for young children** means a product specially **[formulated and]** manufactured for use as a liquid part of the **[progressively]** ~~[diversified]~~ diet of young children **[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements]**.
- 2.1.2 **[Name of product] for young children** ~~[Follow-up formula]~~ is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

**2.2 Other Definitions**

- 2.2.1 The term **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

**3 ESSENTIAL COMPOSITION AND QUALITY FACTORS****3.1 Essential composition**

- 3.1.1 **[Name of product] for young children** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children. The nutritional safety and adequacy of [Name of Product] for young children shall be scientifically demonstrated to support growth and development of young children.
- 3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.
- 3.1.3 (Name of product) for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)\*, as appropriate. The general principles for establishing these levels are identified in Annex I of this standard.

**a) Protein** <sup>1), 2)</sup>

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8	-	-
g/100 kJ	0.43	-	-

<sup>1)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

\* Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in [name of product] for young children should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of [name of product] for young children or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

- 2) The quality of protein shall not be less than 85% of that of casein.

The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.

## b) Lipids <sup>3)</sup>

### Total fat

Unit	Minimum	Maximum	GUL
g /100 kcal	<del>{3.5}</del> or [4.0] or [4.4]	-	-
g /100 kJ	<del>{0.84}</del> or [0.96] or [1.1]	-	-

### α-linolenic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	-
mg /100 kJ	12	-	-

### Linoleic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	300	-	-
mg /100 kJ	72	-	-

- <sup>3)</sup> Partially hydrogenated oils and fats shall not be used in [name of product] for young children.

## c) Carbohydrates

### Available carbohydrates <sup>4)</sup>

Unit	Minimum	Maximum	GUL
g /100 kcal	-	<del>[12.0]</del> or [12.5]	-
g /100 kJ	-	<del>[2.9]</del> or [3.0]	-

- <sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Sugars, other than lactose [or other carbohydrates contributing to the sweet taste of [name of product]] should not exceed [10%] or [20%] of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

*[Mono- and disaccharides], other than lactose, should not exceed 20% of available carbohydrate. [Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.] Sucrose and/or fructose [or other carbohydrates contributing to the sweet taste of [name of product]] should not be added, unless needed as a carbohydrate source. [Other non-carbohydrate ingredients should not be added solely with the purpose of imparting a sweet taste.]*

## [d) Vitamins and Minerals]

### Iron <sup>5)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

- <sup>5)</sup> For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

### Vitamin C <sup>6)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70
mg /100 kJ	2.4	-	17

- <sup>6)</sup> expressed as L-ascorbic acid

### Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	90	-	280
mg /100 kJ	22	-	67

~~[Ratio calcium/phosphorous]~~

Min	Max
{1:1}	{2:1}

**Riboflavin**

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	650
µg /100 kJ	19	-	155

**Vitamin B<sub>12</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg /100 kJ	0.024	-	0.48

**Zinc**

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

**Vitamin A**

Unit	Minimum	Maximum	GUL
µg RE <sup>8)</sup> /100 kcal	60	180	-
µg RE <sup>8)</sup> /100 kJ	14	43	-

<sup>8)</sup> expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

**{Vitamin D}**

Unit	Minimum	Maximum	GUL
µg <sup>9)</sup> /100 kcal	{1.5} or {1.0}	{4.5} or {3.0}	-
µg <sup>9)</sup> /100 kJ	{0.36} or {0.24}	{1.08} or {0.72}	-

<sup>9)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

**Sodium chloride** should not be added to [name of the product] for young children.

**3.1.4** National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breast milk, and take into account the inherent levels of nutrients in cows' milk.

All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.

**3.2 Optional Ingredients**

**3.2.1** In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.

**3.2.2** When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.



**3.2.3** Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

## **9. [LABELLING]**

*The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.*

### **9.1 The Name of the Product**

**9.1.1** *The text of the label and all other information accompanying the product shall be written in the appropriate language(s).*

**9.1.2** *The name of the product shall be [Name of Product] for Young Children as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national {or regional} usage.*

**9.1.3** *The sources of protein in the product shall be clearly shown on the label.*

**9.1.4** *OPTION 1: Split provision 9.1.4 into two:*

**9.1.4(a)** *If [name of animal] milk is the only source of protein[\*], the product may be labelled '[Name of Product] for Young Children based on [name of animal] milk [protein]'.*

**9.1.4(b)** *If [name of plant] is the only source of protein[\*], the product may be labelled '[Name of Product] for Young Children based on [name of plant] [protein]'.*

*[\* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.]*

**OR**

*OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3*

**9.1.5** *A product which contains neither milk nor any milk derivative {shall} {may} be labelled "contains no milk or milk products" or an equivalent phrase.*

### **9.2 List of Ingredients**

**9.2.1** *A complete list of ingredients ~~{including optional ingredients}~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.*

**9.2.2** *The specific name shall be declared for ingredients of animal or plant origin and for food additives. {Food additives may also optionally declare the INS number}.*

### **9.3 Declaration of Nutritive Value**

*The declaration of nutrition information {for [name of product] for young children} shall contain the following information which should be in the following order:*

- d) *the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold {as well as} {or} per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.*
- e) *the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold {as well as} {or} per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.*

- f) In addition, the declaration of nutrients in a) and b) per {serving size and/or per} 100 kilocalories (or per 100 kilojoules) is permitted.

#### 9.4 Date Marking and Storage Instructions

- 9.4.1 The “**Best Before Date**” or “**Best Quality Before Date**” ~~date of minimum durability (preceded by the words “best before”)~~ shall be declared by the day, month and year ~~in uncoded numerical sequence~~ except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] will suffice. ~~The month may be indicated by letters in those countries where such use will not confuse the consumer.~~ [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

- 9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated # [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

#### 9.5 Information for use

- 9.5.1 [Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
- 9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula~~ [product] remaining after feeding should be discarded, shall appear on the label.
- 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. ~~[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]~~
- 9.5.4 ~~{The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use}.~~
- 9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
- ~~{9.5.6~~ The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a [diversified] ~~{balanced}~~ diet.]

#### 9.6 Additional Labelling Requirements

- ~~{9.6.1~~ The label of [name of product] for young children shall have no image, text or representation **[,including pictures of feeding bottles,]** that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label.]
- ~~{9.6.2}~~ Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes[, **and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used**].

**GENERAL PRINCIPLES UNDERPINNING THE SELECTION OF NUTRIENTS FOR THE MANDATORY ESSENTIAL COMPOSITION OF [NAME OF PRODUCT] FOR YOUNG CHILDREN**

The principles for selecting which nutrients must be mandatory:

Evidence to support:

1. Contribution to the nutritional needs of young children where the nutrient is widely inadequate; and/or
2. Contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or
3. The nutritional quality and integrity of product to ensure nutritional safety.

**Appendix III****List of Participants****Codex Members & Codex Member Organisation**

- |                        |                     |                                  |
|------------------------|---------------------|----------------------------------|
| 1. Argentina           | 17. Guyana          | 33. Republic of Korea            |
| 2. Australia           | 18. India           | 34. Republic of Macedonia        |
| 3. Austria             | 19. Indonesia       | 35. Russian Federation           |
| 4. Botswana            | 20. Ireland         | 36. Senegal                      |
| 5. Brazil              | 21. Jamaica         | 37. Singapore                    |
| 6. Canada              | 22. Japan           | 38. South Africa                 |
| 7. Chile               | 23. Kenya           | 39. Sweden                       |
| 8. China               | 24. Malaysia        | 40. Switzerland                  |
| 9. Colombia            | 25. Mexico          | 41. Tanzania                     |
| 10. Costa Rica         | 26. Morocco         | 42. Thailand                     |
| 11. Dominican Republic | 27. Nepal           | 43. United Kingdom               |
| 12. Ecuador            | 28. The Netherlands | 44. Uruguay                      |
| 13. Egypt              | 29. New Zealand     | 45. the United States of America |
| 14. El Salvador        | 30. Norway          | 46. Vietnam                      |
| 15. The European Union | 31. Peru            |                                  |
| 16. France             | 32. The Philippines |                                  |

**Codex Observers**

1. Association of Yoghurts & Live fermented milks (YLFA)
2. Comité Européen des fabricants de sucre (CEFS)
3. Federation of European Specialty Food Ingredients Industries (EUSFI)
4. European Natural Soy foods Manufacturers Association (ENSA)
5. European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)
6. European Vegetable Protein Association (EUVEPRO)
7. Global Organization for EPA and DHA Omega-3s (GOED)
8. Helen Keller International (HKI)
9. International Association of Consumer Food Organizations (IACFO)
10. International Baby Food Action Network (IBFAN)
11. International Council on Amino Acid Science (ICAAS)
12. International Dairy Federation (IDF)
13. International Food Policy Research Institute (IFPRI)
14. Institute of Food Technologies (IFT)
15. International Lactation Consultant Association (ILCA)
16. International Probiotics Association (IPA)
17. International Special Dietary Foods Industries (ISDI)
18. Specialised Nutrition Europe (SNE)